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
EURAND, INC., CEPHALON, INC., and ANESTA AG, Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	:	C. A. No. 09-18-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 the discovery requested 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 confidential lab notebooks and other research and development documents of plaintiffs 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

During a September 15, 2009 status conference, the court deferred ruling on Mylan's request for documents related to plaintiffs' Diffucaps® platform, until plaintiffs provided discovery on secondary considerations of nonobviousness. Plaintiffs' second supplemental response to certain interrogatories was provided on October 5. After that status conference and before further submissions on the discovery dispute occurred, Mylan filed its second answer, defenses and counterclaims on September 30, 2009. In that pleading, Mylan added the affirmative defense and counterclaim of inequitable conduct, wherein it asserts that the '215 patent discloses the same method of measuring the desired release profile as disclosed and claimed in the '793 patent; the inventors of the '793 patent claimed a formulation[1] 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 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 asserts that based on such conduct, the '793 patent is unenforceable due to inequitable

[1] The '215 patent deals methylphenidate formulations based on the Diffucaps® technology, involving immediate release (IR) beads and extended release (ER) beads, which allows a therapeutical release of the mediation 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.

conduct.

During the September 15 hearing, the court advised that an explanation of the technology involved would be helpful. As a result of the parties submissions on October 9, it appears that plaintiffs' trademark, Diffucaps®, describes various drug formulations where a drug is coated onto neutral cores, with those cores coated with a release controlled polymer and the resulting beads are then filled into gelatin capsules. According to plaintiffs, each drug is formulated differently, with the cyclobenzaprine formulations claimed in the '793 patent falling within the overview of the Diffucaps® trademark. As emphasized by plaintiffs, a number of other patented drug formulations which employ different formulation technologies are also marketed under the Diffucaps® trademark.

Thereafter, another hearing was held on October 13. Further submissions were allowed. Those submissions were filed on October 15, 2009. An additional submission was filed by Mylan on October 19, 2009 which related to the USPTO rejection on October 16, 2009 on the basis of obviousness a pending continuation of the '793 patent's priority application. According to Mylan, in that continuation, plaintiffs are seeking additional claims to the same formulation as in the '793 patent by eliminating the requirement of a plasticizer in the extended-release layer. Mylan's submission invited a response from plaintiffs, which was filed on October 20, 2009.[2]

Parties' Contentions

According to its letter of October 15, Mylan presently requests production of

[2] After the hearings, this discovery matter was referred to Magistrate Judge Thynge for decision.

"development progress reports and documents concerning the compositions of and testing relating to the two properties claim claimed in the '793 patent for two prior art Diffucaps products – methylphenidate and amitriptyline; and . . . with respect to other Diffucaps formulations." It purportedly only requires an interrogatory response which describes "the composition of each such dosage form that has been commercialized prior to the '739 patent priority date and its release profile as tested in accordance with the method recited in the '739 patent." It also requests that plaintiffs "be held to their representation . . . that non-confidential documents relating to these formulations have not been withheld." Mylan further demands that plaintiffs be ordered to provide "prompt and specific" disclosure of any evidence on which they rely to support the secondary considerations of nonobviousness, as well as documents to, from or generated by the two named inventors of the '793 patent relating to amitriptyline and the same materials from inventor Clevenger regarding methylphenidate.[3] Mylan contends that the asserted claims of the '739 patent are directed to compositions that exhibit certain characteristics when tested, pointing to parts of claim 1. It maintains that the inherent characteristics of the "dosage form may be established through non-prior art information" which includes internal test data. Mylan notes that the Diffucaps platform has been the vehicle for other prior art extended-release formulations, such as methylphenidate and amitriptyline, and argues that the '215 patent, which deals with methylphenidate, discloses formulations very similar to those in the '793 patent. It contends that the amitriptyline compound is *almost identical* to cyclobenzaprine and has some similar

[3] It does not appear, as Mylan suggested during the October 13 hearing, that the additional discovery is truly limited.

properties. As a result, according to Mylan, a direct nexus exists between those Diffucaps formulations, which include inherent properties, to the '739 patent that claims cyclobenzaprine formulations.

Mylan also asserts that plaintiffs' generalized interrogatory response regarding secondary factors is inadequate and may evince an assertion that the '793 formulation was difficult to develop. It raises a concern that plaintiffs' delay could potentially foreclose timely fact discovery of rebuttal evidence countering nonobviousness.

Mylan's third argument relates to its first, that documents should be discoverable from certain inventors on amitriptyline and methylphenidate, which discovery it purports is not burdensome.

In support of its arguments, Mylan relies primarily on *Schering Corp. v. Geneva Phams., Inc.*,[4] *In re Napier*,[5] and *In re Grasselle*.[6] It also points to the findings by the USPTO in its recent rejection based on obviousness of the pending continuation as proving the relevance of prior art non-cyclobenzaprine Diffucaps® formulations.[7] This recent Office Action by the examiner is not final.

Plaintiffs point out that although Eurand uses the trademark "Diffucaps®" to describe and market a number of formulation technologies, each drug involved is

---

[4] 339 F.3d 1373, 1380 (Fed. Cir. 2003).

[5] 55 F.3d 610 (Fed. Cir. 1995).

[6] 713 F.2d 731 (Fed. Cir. 1983.

[7] The examiner based his rejection on combination of the teachings of the '215 patent, dealing with methylphenidate, the '228 patent, which the examiner concluded teaches a multiparticulate osmotic dosage form comprising cyclobenzaprine and Razaghi, et. al. (cited in Eurand's IDS), which teaches an oral osmotic of cyclobenzaprine. The examiner found that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the '215 patent in view of the '228 patent or Razaghi, et. al. See Ex. A to D.I. 104.

formulated differently. It notes that Mylan's request, which is directed to the formulation and development of other drugs marketed under the Diffucaps® trademark, are irrelevant to the development of cyclobenzaprine formulations claimed in the '793 patent. Plaintiffs argue that the production of such confidential documents is burdensome, not prior art and not relevant for Mylan's obviousness contentions. They note that Mylan's recent inequitable conduct allegation, which asserts that the named inventor failed to disclose the '215 patent during the pendency of the '793 patent application, does not make the other drug documents Mylan seeks relevant. Moreover, according to plaintiffs, Mylan's argument for such discovery in relation to inequitable conduct is that the formulations of other drugs *might* develop evidence in support of this defense. Plaintiffs dispute Mylan's application of the *Schering* case, which dealt with inherent anticipation, since inherency and obviousness are distinct concepts, and thus the information requested regarding methylphenidate formulations disclosed in the '215 patent, as well as, other drugs formulations, are irrelevant to an obviousness defense in the present matter, citing *Life Technologies, Inc. v. Clontech Laboratories, Inc.*[8] Regarding Mylan's argument that such documents are relevant to secondary considerations of nonobviousness, plaintiffs note that Mylan fails to cite any authority to support that proposition and obviousness/nonobviounsess is judged by the standard of one of ordinary skill in the art. They further maintain that the Patent Office's recent rejection of claims of another application which was based on publically available

[8] 224 F.3d 1320, 1325 (Fed. Cir. 2000). Specifically, plaintiffs contend that "a so-called inherent feature of the prior art may only be relied upon to establish obviousness if the inherency would have been obvious to one or ordinary skill in the art at the time the invention was made." D.I. 102 (emphasis in original).

references is misplaced, since the documents sought are not prior art and therefore, "legally irrelevant." Plaintiffs also cite a number of cases in support of their propositions.[9]

Discussion

Under § 103, a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art . . ." at the time the invention is made. Although obviousness is a question of law, it is determined after answers to certain fact questions have been found: the scope and content of the prior art; the differences between that art and the claims at issue; the level of ordinary skill in the art; and whatever objective evidence (secondary considerations) may be present.[10] Thus, obviousness and nonobviousness are based on objective standards. Mylan's contentions, in part, for the various documents requested rely on obviousness and nonobviousness.

The inequitable conduct recently alleged by Mylan centers on the purported failure by one of the inventors and his counsel to disclose known material information, specifically, the '215 patent, during the prosecution of the '793 patent, coupled with the

---

[9] *See Riverwood Int'l. Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1576 (Fed. Cir. 1986), overruled on other grounds by *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004).

[10] *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also, Vandeberg v. Dairy Equip. Co.*, 740 F.2d 1560 (Fed. Cir. 1984) (wherein the Federal Circuit made it clear that secondary considerations, objective evidence, is the fourth factor under the *Graham* analysis for obviousness).

intent to deceive the examiner. Its allegations of inequitable conduct do not include affirmative misrepresentations of material fact or the submission of false material information.

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."[11]

"Information is material when there is a substantial likelihood that a reasonable Examiner would have considered the information important in deciding whether to allow the application to issue as a patent."[12] However, since patentability is evaluated from the perspective of one of ordinary skill in the art, "information regarding the subjective motivations of inventors is not material."[13] Moreover, "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute."[14] Further, as recognized in *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*[15], "[o]ne's own work may not be considered prior art in the absence of a statutory basis . . . ."[16]

Contrary to Mylan's argument, the *Micron Tech.* case does not stand for the proposition that internal non-public documents are automatically discoverable or

---

[11] *Stowe Woodward L.L.C. v. Sensor Products, Inc.*, 230 F.R.D. 463, 466 (W.D. Va. 2005) (quoting *Solarex Corp*. *v. Arco Solar, Inc.*, 121 F.R.D. 161, 178 (E.D.N.Y 1988).
[12] *Life Techs., Inc.*, 224 F.3d at 1325.
[13] *Id.*
[14] *Id. See* 35 U.S.C. § 103(a).
[15] 748 F.2d 645 (Fed. Cir. 1984).
[16] *Riverwood Int'l. Corp.*, 324 F.3d at 1355.

relevant. That case dealt with the analysis of spoliation, which involved extensive destruction of innumerable documents relating to all aspects of the defendant's business. Although the single quote cherry-picked by Mylan came from a discussion of the relevance of the destroyed documents in relation to unenforceability, the court also noted that the defenses of obviousness and anticipation depend on external or publically available evidence.[17] In the instant matter, the inequitable conduct defense raised by Mylan, failure to disclose the '215 patent, relies on publically available information.[18]

Contrary to Mylan's suggestion, *Schering* does not stand for the proposition that non-prior art data (or non-public data) is relevant to an objective inquiry. As noted in *Schering*, which involved an analysis of inherent anticipation, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristics is necessarily present, or inherent, in the single anticipating reference."[19] *Schering* reiterated the principle that "inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure."[20] *Schering* focused on whether anticipation could be found "when the entire structure of the claimed subject matter is inherent in the prior art."[21] In finding that

---

[17] *Micron Tech.*, 255 F.R.D. at 151 n. 59. As noted by the court, such defenses do not depend on internal evidence, but rather on prior art references, which by definition "must be publically available." *Id*.

[18] The '793 patent was filed on November 14, 2003, while the '215 patent issued on February 5, 2002.

[19] *Schering*, 339 F.3d at 1377 (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)).

[20] *Id.*

[21] *Id.*

anticipation existed, the Federal Circuit analyzed the prior art, specifically a patent, to determine whether it sufficed as an enabling disclosure. The court explicitly noted that secret testing before the critical date was irrelevant.[22]

That the inherent teaching of a prior art reference is applicable to obviousness does not make the information requested by Mylan relevant since, as explained previously, obviousness is an objective legal construct, measured by whether the inherency would have been obvious to one skilled in the art.[23]

Moreover, the fact that this court has previously discussed the similarities between amitriptyline and cyclobenzaprine in another patent case[24] does not mean such similarities are relevant to the present matter on an unrelated patent. In *Merck*, the Federal Circuit upheld the finding of inequitable conduct by the lower court not only because *published* articles and studies were withheld, but also because of misrepresentations made to the PTO regarding the lack of side effects of cyclobenzaprine, the drug involved in the patent in question.

Similarly, the present initial findings of the examiner are also irrelevant to the discovery issue at hand. First, the findings by the examiner are preliminary and not

---

[22] *Id*. at 1380.

[23] *See In re Grasselli*, 713 F.2d 731, 739 (Fed. Cir. 1983) (where the court considered affidavits filed by the intervenor during re-exam in support of its assertions that the reissued application was anticipated. As the court noted, it considered such extraneous materials because they were evidence of inferences of inherency, and not because they constituted prior art. In reversing the PTO Board of Appeals finding of obviousness, the court noted that absent sufficient evidence of inherency in the prior art, "obviousness cannot be predicated on that which is unknown." *Id.*). *See also*, *In re Napier*, 55 F.3d 610, 611 (Fed. Cir. 1995).

[24] *See Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418 (Fed. Cir. 1989). The patent-at-issue claimed a method of using cyclobenzaprine for treatment of certain types of skeletal disorders, in which the selectivity of that drug was emphasized.

final. The time period for plaintiffs' response to the examiner's comments has not expired. Second, Mylan is asking to "get behind" the '215 patent, as well as, any other research by Eurand and the inventors, including unpublished laboratory notebooks and other materials regarding methylphenidate and other drug formulations. It argues that such documents *may* contain data which shows that those formulations inherently exhibit the release profile in the '793 patent, using the same testing method and reaction conditions claimed in that patent. Assuming *arguendo* that the examiner's initial determination is pertinent to the present dispute, it refutes Mylan's argument that the discovery requested is necessary. As noted herein, and emphasized by Mylan, the examiner made his obviousness finding on the basis of the '215 patent and what it teaches.

In conclusion, for the reasons contained herein, Mylan's request for the documents and materials noted in its letters of October 9, 2009 and October 15, 2009 is denied.

However, Mylan's request for disclosure of the factual evidence upon which plaintiffs may rely concerning the secondary considerations of the claimed formulation is not unreasonable. Plaintiffs shall supplement their present responses to interrogatories and requests for production propounded by Mylan or jointly by defendants regarding the factual evidence on which they presently rely in support of secondary considerations of nonobviousness, recognizing their continuing obligation to timely update such responses under Fed. R. Civ. P. 26(e) as additional information becomes available as a result of further discovery. Those responses shall be provided on or before December 23, 2009.

Therefore,

IT IS ORDERED that consistent with the findings and rulings contained herein, Mylan's request for documents and other materials contained in its letters of October 9 and October 15, 2009 is denied..

IT IS FURTHER ORDERED that plaintiffs shall supplement their responses to interrogatories and requests for production propounded by Mylan or jointly by defendants regarding the factual evidence on which they presently rely in support of secondary considerations of nonobviousness.

Dated: December 9, 2009 /s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE