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

BONE CARE INTERNATIONAL, LLC and GENZYME CORPORATION,	)	
Plaintiffs,	)	
	)	Case No.: 08-cv-1083
v.	)	
	)	Judge Robert M. Dow, Jr.
PENTECH PHARMACEUTICALS, INC., and COBREK PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Bone Care International, LLC and Genzyme Corporation (collectively, "Plaintiffs") brought this patent infringement suit against Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively, "Defendants") for infringement of United States Patent No. 5,206,116 ("'116 Patent"). Defendants asserted affirmative defenses and counterclaims [227] alleging, *inter alia*, that Claim 7 of the '116 Patent is unenforceable because Plaintiffs engaged in inequitable conduct in prosecution of the patent before the United States Patent and Trademark Office ("PTO"). Defendants also seek to recover attorneys' fees pursuant to 35 U.S.C. § 285. Currently before the Court is Plaintiffs' motion for summary judgment [336] on Defendants' inequitable conduct Affirmative Defenses F and G and Counterclaim IX. For the reasons stated below, Plaintiffs' motion for summary judgment [336] is denied.

I. Background

A. Factual Background

The Court takes the relevant facts primarily from the parties' Local Rule ("L.R.") 56.1[1] statements: Plaintiffs' Statement of Facts ("Pls.' SOF") [337], Defendants' Response to Plaintiffs' Statement of Facts and Statement of Additional Facts ("Defs.' Resp. to Pls.' SOF" and "Defs.' SOF") [382], and Plaintiffs' Response to Defendants' Statement of Additional Facts ("Pls.' Resp. to Defs.' SOF") [396].[2]

The '116 Patent establishes Plaintiffs' right to make, use, or sell 1αOH-vitamin D_2 and related vitamin D compounds, collectively known as doxercalciferol, to treat patients with hyperparathyroidism secondary to end-stage renal failure. A simple sketch of the science relevant to the '116 Patent follows: Vitamin D is necessary to the body's absorption of calcium. Patients with end-stage renal failure cannot absorb calcium properly due to the inability of the

[1] Local Rule 56.1 requires that statements of facts contain allegations of material fact and that factual allegations be supported by admissible record evidence. See L.R. 56.1; *Malec v. Sanford*, 191 F.R.D. 581, 583-85 (N.D. Ill. 2000). The Seventh Circuit has confirmed repeatedly that a district court has broad discretion to require strict compliance with L.R. 56.1. See, *e.g.*, *Koszola v. Bd. of Educ. of the City of Chicago*, 385 F.3d 1104, 1109 (7th Cir. 2004); *Curran v. Kwon*, 153 F.3d 481, 486 (7th Cir. 1998) (citing *Midwest Imports, Ltd. v. Coval*, 71 F.3d 1311, 1317 (7th Cir. 1995 (collecting cases)). Where a party has offered a legal conclusion or a statement of fact without offering proper evidentiary support, the Court will not consider that statement. See, *e.g.*, *Malec*, 191 F.R.D at 583. Additionally, where a party improperly denies a statement of fact by failing to provide adequate or proper record support for the denial, the Court deems that statement of fact to be admitted. See L.R. 56.1(a), 56.1(b)(3)(B); see also *Malec*, 91 F.R.D. at 584. The requirements for a response under L.R. 56.1 are "not satisfied by evasive denials that do not fairly meet the substance of the material facts asserted." *Bordelon v. Chicago Sch. Reform Bd. of Trs.*, 233 F.3d 524, 528 (7th cir. 2000). The Court disregards any additional statements of fact contained in a party's response brief but not in its L.R. 56.1(b)(3)(B) statement of additional facts. See, *e.g.*, *Malec*, 191 F.R.D. at 584 (citing *Midwest Imports*, 71 F.3d at 1317). Similarly, the Court disregards a denial that, although supported by admissible record evidence, does no more than negate its opponent's fact statement. In other words, it is improper for a party to smuggle new facts into its response to a party's L.R. 56.1 statement of fact, and the Court will disregard such facts. See, *e.g.*, *Ciomber v. Cooperative Plus, Inc.*, 527 F.3d 635, 643 (7th Cir. 2008).

[2] Both parties argue that the other failed to comply with the formal and substantive requirements of L.R. 56.1. To the extent that such assertions have merit, the Court reiterates that it will disregard any legal argument, unsupported inferences, or other non-factual assertions that appear in the L.R. 56.1 statements.

kidneys to metabolize vitamin D. This leads to low blood levels of calcium ("serum calcium")—a condition known as hypocalcemia. Hypocalcemia signals the parathyroid gland to release increased amounts of parathyroid hormone ("PTH"). PTH in turn triggers the release of calcium from the bones to the bloodstream. In a healthy human, the PTH-triggered release of calcium from the bones would resolve the hypocalcemia. In a patient suffering end-stage renal failure, however, the calcium released from the bones cannot be metabolized because the kidneys cannot process vitamin D. As a result, serum calcium levels remain low and PTH levels remain correspondingly high. This condition is known as hyperparathyroidism secondary to end-stage renal failure, or secondary hyperparathyroidism. As more calcium is leached from the bones, patients with secondary hyperparathyroidism begin to experience hyperparathyroid bone disease, which presents as bone abnormalities and loss of bone mass density. Claim 7 of the '116 Patent established a method for administering doxercalciferol to prevent or mitigate hyperparathyroid bone disease by lowering or maintaining lowered levels of PTH in patients suffering secondary hyperparathyroidism.

The long and winding history of the '116 Patent's prosecution began on August 2, 1988, with the filing of Patent Application No. 227,371 ("Parent Application"). During the ensuing five years, Plaintiffs filed a series of patent applications as continuation or continuations-in-part ("CIP") applications[3] of the Parent Application.[4] On April 3, 1995, Plaintiffs filed Patent

[3] Pursuant to 35 U.S.C. § 120, a continuation-in-part patent application is one that discloses a substantial portion of the subject matter disclosed in an earlier-filed patent application (known as a "parent application"), and claims the benefit of (or "claims priority to") the parent application's earlier filing date for that subject matter, which is thus termed the "priority date" or "priority filing date." A CIP application may also claim subject matter not disclosed in the Parent Application; that additional subject matter is entitled to the benefit only of the later filing date of the CIP application. M.P.E.P. § 201.08 (8th ed. 2001).

[4] Specifically, Patent Application No. 119,895 was filed on September 10, 1993, as a continuation of Patent Application No. 812,056, which was filed on December 17, 1991, as a continuation of Patent

Application No. 415,488 ("'488 Application") as a CIP application of the series of patent applications relating back to the Parent Application. On June 26, 1996, a PTO examiner interviewed Plaintiffs regarding the '488 Application's relation to two prior art references. The following day, Plaintiffs submitted amendments to the '488 Application, asserting that the application related back to the Parent Application. As such, they argued, the '488 Application "claimed priority," or was entitled, to the August 2, 1988, filing date of the Parent Application (which preceded the prior art references) rather than the April 3, 1995, filing date (which post-dated those patents). On February 11, 1997, the PTO issued the '116 Patent on the basis of the '488 Application. The patent expires on February 11, 2014.

On April 6, 2000, the FDA approved Plaintiff Genzyme's New Drug Application ("NDA") for doxercalciferol. Plaintiffs began producing and selling the drug under the brand name Hectorol. Defendant Pentech later submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture, use, or sell a generic version of Hectorol. Pentech alleged in the ANDA that its application did not infringe on the '116 Patent because the '116 Patent was invalid and unenforceable.

B. Procedural Background

Plaintiffs filed a complaint against Pentech and Cobrek claiming that Pentech's ANDA infringed on the '116 Patent, and seeking a declaratory judgment, injunctive relief, litigation costs, attorneys' fees, and, in the event that Defendants proceed with the manufacture, use, or sale of doxercalciferol prior to the 2014 expiration of the '116 Patent, money damages. [197] In their answer, Defendants asserted various affirmative defenses and counterclaims alleging, *inter*

Application No. 596,412, which was filed on August 17, 1990, as a continuation of the August 2, 1988, Parent Application.

alia, that Claim 7 of the '116 Patent is invalid because Plaintiffs engaged in inequitable conduct in the prosecution of the '116 Patent. [227]

Plaintiffs moved to dismiss Defendants' inequitable conduct Affirmative Defenses A-G. [241] The Court granted in part and denied in part Plaintiffs' motion, dismissing Defendants' Affirmative Defenses A, B, C, and E, but denying the motion as to Affirmative Defenses D, F, and G. [327] Plaintiffs now seek summary judgment on Affirmative Defenses F and G, as well as on Counterclaim IX.

II. Legal Standard

Summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

To survive a motion for summary judgment, the non-movant must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250. A mere showing that there is "some metaphysical doubt as to the material facts" is not enough. *Matsushita Elect. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). There must be more than a "mere existence of a scintilla of evidence in support of the [non-movant's] position" that a jury could reasonably find in the non-movant's favor. *Anderson*, 477 U.S. at 252. When the non-movant "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the

burden of proof at trial," summary judgment is warranted. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The party moving for summary judgment bears the burden of establishing that the non-movant has not presented any genuine issue of material fact. See *Celotex*, 477 U.S. at 323. The Court must then "construe the facts and draw all reasonable inferences in the light most favorable to a nonmoving party." *Foley v. City of Lafayette*, 359 F.3d 925, 928 (7th Cir. 2004).

III. Analysis

Plaintiffs seek summary judgment on Defendant's inequitable conduct Affirmative Defenses F and G, and on Counterclaim IX. Defendants allege in Affirmative Defense F that Plaintiffs engaged in inequitable conduct in filing the '488 application because they intentionally failed to disclose to the PTO prior art—abstracts and posters that Dr. Bishop, one of the '116 inventors, co-authored in 1989 and 1993 ("Gallagher Abstracts")—that were material to that Application and preceded its 1995 filing date. As a result of this inequitable conduct, Defendants argue, Claim 7 of the '116 Patent is invalid and unenforceable. In Affirmative Defense G, Defendants contend that Claim 7 of the '116 is unenforceable because Plaintiffs engaged in inequitable conduct when they submitted to the PTO a 1994 article co-authored by Dr. Bishop despite knowing that the article obscured the existence of the Gallagher Abstracts. In Counterclaim IX, Defendants seek attorneys' fees pursuant to 35 U.S.C. § 285 on the ground that Plaintiffs engaged in litigation misconduct by arguing that Claim 7 of the '116 Patent is entitled to a 1988 priority filing date. In short, all three of Defendants' affirmative defenses and counterclaims at issue here are premised on the argument that Claim 7 of the '116 Patent is not entitled to the August 2, 1988, priority filing date of the Parent Application, but rather is entitled only to the April 3, 1995, filing date of the '488 Application.

Plaintiffs argue that summary judgment is warranted on Affirmative Defenses F and G and Counterclaim IX because no reasonable trier of fact could find that Claim 7 is not entitled to the benefit of the 1988 priority filing date of the Parent Application. According to Plaintiffs, failure to disclose the Gallagher Abstracts to the PTO is not inequitable conduct rendering Claim 7 invalid, because the 1988 priority filing date *precedes* the Gallagher Abstracts, and the Abstracts are not, therefore, material *prior* art subject to mandatory disclosure.[5]

Defendants do not dispute that the Gallagher Abstracts post-date the 1988 filing date of the Parent Application. And they concede that, if Plaintiffs are correct in claiming that Claim 7 of the '116 Patent is entitled to the benefit of the 1988 priority filing date, the three affirmative defenses and counterclaims at issue here must fail. Defendants maintain, however, that Claim 7 is entitled only to the benefit of the 1995 filing date of the '488 Application. As such, they argue that the Gallagher Abstracts constitute prior art that anticipated Claim 7, and that Plaintiffs' failure to disclose the Abstracts and efforts to obscure their existence rise to the level of inequitable conduct rendering Claim 7 invalid.

This motion for summary judgment requires the Court first to determine, as a threshold matter, which party bears the burden of proving whether Claim 7 of the '116 Patent is entitled to the benefit of the August 2, 1988, priority filing date, and then to assess whether any genuine issue of material fact exists as to Claim 7's entitlement to the benefit of the priority filing date. The Court addresses each issue in turn.

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[5] Materiality is one of two substantive elements of a claim of inequitable conduct. The other is intent to deceive. See *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007) (holding that "[a] breach of [the] duty [of candor]—including affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information—coupled with an intent to deceive, constitutes inequitable conduct"); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). The Federal Circuit recently held in *Trading Techs. Int'l v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010), that references that post-date a patent application's filing date are not "material" for purposes of patentability of the application's claims.

A. The Filing Date of the '116 Patent

1. Burden of Proof in Establishing Whether the '116 Patent Is Entitled to the Benefit of the Priority Filing Date

The parties appear to agree that a plaintiff bears the initial burden of presenting evidence to prove entitlement to an earlier priority date in a CIP application. See *PowerOasis, Inc. LLC v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008); *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1574 (Fed. Cir. 1985). They disagree, however, as to when that burden arises, how it is met, and whether Plaintiffs have satisfied it here.

It is well-settled that an issued patent is entitled to a presumption of validity. 35 U.S.C. § 282; *Radio Corp. of America v. Radio Eng'g Labs, Inc.*, 293 U.S. 1, 7-8 (1934); *Ralston Purina*, 772 F.2d at 1573. The presumption follows from the principle that deference is due to the PTO's decision to issue a patent when the PTO has considered all evidence bearing on the patent's validity. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984). The presumption of validity of an issued patent can be rebutted only upon a showing by clear and convincing evidence. *Id.* (citing *Radio Corp. of America*); see also *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983).

The rebuttable presumption of validity that attaches to an issued patent extends to a CIP application's claim to the priority filing date of a parent application in cases where the PTO *explicitly* has made a finding that the CIP application is entitled to the benefit of that date. See *PowerOasis*, 522 F.3d at 1305; see also *Ralston Purina*, 772 F.2d at 1574 (holding that "[a] party asserting invalidity based on 35 U.S. § 112 bears no less a burden and no fewer responsibilities than any other patent challenger"). The Federal Circuit has cautioned, however, that it is not incumbent upon a PTO examiner to make such a finding. *PowerOasis*, 522 F.3d at 1305. The PTO need not make a finding regarding the filing date unless, during prosecution of the CIP

application, there is an interference or rejection of a claim based on prior art preceding the CIP application's filing date. *Id.* In the event of an interference or rejection, the applicant may present evidence that the CIP application overcomes the prior art by showing that the application is entitled to the priority filing date of the parent application. *Id.* at 1304-05. The PTO examiner then may make an explicit finding as to whether the CIP application is entitled to the benefit of the priority date. *Id.* Deference is accorded to the examiner's finding, and it is entitled to a presumption of validity. A party challenging entitlement to the priority date can overcome the presumption only upon a showing of clear and convincing evidence. *Id.*; see also *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008). When there is no occasion for the PTO to make that determination (*i.e.*, when there has been no interference or prior art claim), the applicant need not prove to the PTO entitlement to the priority date, and the PTO need not make a finding to that effect. See *PowerOasis*, 522 F.3d at 1305; *Tech. Licensing Corp.*, 545 F.3d at 1327-28. In that event, no presumption of validity attaches to a priority filing date later claimed by the patentee.

In sum, in a dispute as to a CIP patent's validity based on a claim of interceding prior art, the party arguing invalidity of a CIP patent (here, Defendants) bears the burden of producing evidence that the prior art preceded the filing date of the CIP application. *Tech. Licensing Corp.*, 545 F.3d at 1327. The party claiming a priority date for the patent (here, Plaintiffs) then must prove that the prior art does not pre-date the CIP application because the application is entitled to the benefit of a priority filing date that precedes the prior art. *Id.* In the event of an interference or rejection, that party may prove the CIP application's entitlement to the priority filing date during prosecution of the patent before the PTO, and the examiner then may make an explicit finding as to the correct filing date of the application. If the examiner does not make such a

finding, the party claiming priority must prove entitlement to the priority filing date before the court. *PowerOasis*, 522 F.3d at 1304-05. After the party claiming priority has satisfied its burden, the burden "shifts to the proponent of the invalidity defense * * * to convince the court that [the opposing party] is not entitled to the benefit of the earlier priority date." *Tech. Licensing Corp.*, 545 F.3d at 1327. Of course, in a summary judgment motion, the party claiming invalidity need only convince the court that genuine issues of material fact exist such that the trier of fact reasonably could find that the patent is entitled only to the later filing date.

Here, there was no intervention or rejection of Claim 7 during prosecution of the '488 Application.[6] The PTO examiner therefore had no occasion to make a finding regarding the filing date of Claim 7 of the '488 Application.[7] Plaintiffs asserted to the PTO examiner in their amendments of June 27, 1996, that the '488 Application related back to the Parent Application, and that it was thus entitled to the priority filing date of August 2, 1988. Because the PTO thereafter issued the patent, Plaintiffs argue that the examiner implicitly "accepted" their assertion regarding the priority date. However, there is no office action from the PTO in the '116 Patent's file history that indicates that the examiner *explicitly* made such a determination. See *PowerOasis*, 522 F.3d at 1304-05 (ruling that examiner's finding as to priority date must be "explicit"); *Ralston Purina*, 772 F.2d at 1574 (same).

Because the examiner did not determine priority explicitly, no presumption of validity attaches to Plaintiffs' claim as to priority date. The burden therefore rests on Plaintiffs to prove to the Court that Claim 7 of the '116 Patent is entitled to the August 2, 1988, priority date of the

[6] Claim 7 of the issued '116 Patent was originally designated Claim 17 in the '488 Application. For the sake of simplicity, the Court refers to the claim in question as Claim 7 in discussing both the prosecution of the '488 Application and the '116 Patent that ultimately issued.

[7] On June 27, 1996, Plaintiffs amended several claims in the '488 Application to distinguish them from two previously issued patents. However, Claim 7 was not among the claims amended. The only change to the application bearing on Claim 7 in the June 27, 1996, amendments concerned the relate-back clause.

Parent Application. The Court turns its attention to whether there is a triable issue of fact on that question.

2. The '116 Patent's Entitlement to the Priority Filing Date

Section 120 of Title 35 of the U.S. Code provides that a CIP application is entitled to the benefit of the priority date of a parent application so long as the parent application comports with the three specification requirements enumerated in the first paragraph of 35 U.S.C. § 112. These requirements are: written description, enablement, and best mode. The parties disagree as to whether the '116 Patent's Parent Application meets the written description and enablement requirements of § 112.[8]

a. Written Description Requirement

A patent application to which inventors later claim priority (*i.e.*, a parent application) must "contain a written description of the invention and process of making and using it * * *." 35 U.S.C. § 112, ¶ 1. The written description requirement is satisfied when "the disclosure of the [invention in the parent application] reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

The test is a flexible one, "requir[ing] an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art ("POSA"). Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id*. The original application need not recite the claimed invention *in haec verba*—that is, in exactly the same terms as the later application does—but it must do more than merely render the invention

[8] The parties agree that the best mode requirement is not at issue here.

obvious. *Id.* at 1352. Although the specification "must *describe* the claimed invention with all its limitations" (*Tronzo v. Biomet*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (emphasis added)), a failure to "*specifically* mention a limitation that later appears in the claims is not * * * fatal * * * when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." *All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F.3d 774 (Fed. Cir. 2002) (emphasis added). It is sufficient for purposes of the written description requirement that a POSA would find it "reasonably clear what the invention is and that the patent specification conveys that meaning." *Id.*

Whether a patent application complies with the written description requirement is a question of fact. *Ariad*, 598 F.3d at 1352. The inquiry is "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis*, 522 F.3d at 1307. Thus, the question presented here is whether there is any genuine issue of material fact as to whether a POSA reading Plaintiffs' Parent Application would understand that application to describe the same invention later set forth in Claim 7 of the '116 Patent.

Plaintiffs argue that Example 4 of the Parent Application describes the invention set forth in Claim 7 of the '116 Patent in terms that, although not identical, satisfy the written description requirement of § 112. Claim 7 is construed as inventing:

> A method for lowering or maintaining lowered serum parathyroid hormone in human patients suffering from hyperparathyroidism secondary to end-stage renal disease, comprising: administering to said patients an effective amount of 1α-OH-vitamin D2 [doxercalciferol] to lower and maintain lowered serum parathyroid hormone levels.

Example 4 describes a hypothetical clinical trial involving 30 "men and women with renal disease who are undergoing chronic hemodialysis." See Pls.' SOF, Decl. of Susan Flanders, Ex.

B. [339-3] Half of the patients would receive doxercalciferol, and half would receive a placebo. Results of the trial would show that the patient group treated with doxercalciferol would experience "normalized serum calcium levels, stable values for total body calcium, and stable radial and spinal bone densities relative to baseline values." *Id.* The placebo group, by contrast, would experience "frequent hypocalcemia [and] significant reductions in total body calcium and radial and spinal bone density." *Id.*

According to Plaintiffs, a POSA in 1988 would understand that Example 4 and Claim 7 described the same treatment for the same medical condition with the same beneficial results, although they did so using different terminology. Specifically, Plaintiffs argue that a POSA would understand Example 4's description of patients experiencing renal failure and undergoing chronic hemodialysis whose serum calcium levels and bone density improved when treated with doxercalciferol, to mean that doxercalciferol was being used to treat patients with secondary hyperparathyroidism by lowering their PTH, *i.e.,* the same invention described in Claim 7. In support of this claim, Plaintiffs point to, *inter alia*, the following:

* A POSA in 1988 would understand that patients in renal failure undergoing chronic hemodialysis (*i.e.*, those described in Example 4 of the Parent Application) have end-stage renal disease (*i.e.*, the condition described in Claim 7 of the '116 Patent);

* A POSA in 1988 would understand that "at least a portion" of the patients described in Example 4 were suffering from secondary hyperparathyroidism (as described in Claim 7);

* A POSA in 1988 would understand that low serum calcium levels (hypocalcemia) are associated with secondary hyperparathyroidism, and thus with an increase in PTH levels; and

* A POSA in 1988 would understand that increasing serum calcium would be a key component in the treatment of patients with secondary hyperparathyroidism.

Based on the POSA's understanding of these medical synonyms, Plaintiffs argue, Example 4 describes the same invention as does Claim 7—namely, that treatment with doxercalciferol lowers or maintains lowered PTH levels in patients with hyperparathyroidism secondary to end stage renal failure.

Defendants acknowledge that a disclosure need not be *in haec verba* to satisfy the written description requirement of § 112. Nonetheless, they contend that the absence of the term "secondary hyperparathyroidism" in Example 4 is fatal to Plaintiffs' claim to priority. Specifically, Defendants assert that although it is evident based on the disclosures in Example 4 that the patients in question had end-stage renal failure, experts disagree on whether a POSA in 1988 would understand that all or even most of those patients would have secondary hyperparathyroidism. In support of their argument, Defendants note the testimony of an expert that less than half of the patients described in Example 4 probably would have experienced secondary hyperparathyroidism. Defs.' Resp. to Pls.' SOF ¶ 25. Another expert stated that a majority would have secondary hyperparathyroidism. Defs.' Resp. to Pls.' SOF ¶ 28. Still another expert simply affirmed that "some portion" of such patients would have secondary hyperparathyroidism. Defs.' Resp. to Pls.' SOF ¶¶ 27, 35.

The record is clear that expert opinion differs as to whether a POSA would find that the specification in Example 4 conveys an invention for treatment of secondary hyperparathyroidism. A trier of fact thus reasonably could find that Plaintiffs failed to satisfy the written description requirement and, accordingly, failed to prove entitlement to the benefit of the 1988 priority date. Consequently, the underlying questions as to whether (1) the Gallagher Abstracts constitute prior art material to the '488 Application and (2) Plaintiffs engaged in inequitable conduct in failing to disclose them to the PTO turn on genuine issues of fact to be

resolved at trial with the benefit of cross-examination of the experts to resolve the ambiguities in the experts' assertions that the parties have debated in the briefing on this motion. See, *e.g.*, *Vas-Cath*, 935 F.2d at 1567 (holding that failure of opposing party to refute expert declaration gave rise to a genuine issue of material fact inappropriate for summary disposition) (citing *Hesston Corp. v. Sloop*, 1988 U.S. Dist. LEXIS 1573, at *13 (D. Kan. 1988), for the proposition that "summary judgment on § 112 'written description' issue [is] inappropriate where resolution of what parent disclosure conveyed to those skilled in the art may require examination of experts, demonstrations and exhibits"). The Court therefore denies Plaintiffs' motion for summary judgment on Affirmative Defenses F and G.[9]

b. Enablement Requirement

The second specification required under 35 U.S.C. § 112, ¶ 1, to claim priority to a parent application is enablement. A patent specification is enabling for purposes of 35 U.S.C. § 112, ¶ 1, if it "teach[es] those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citation omitted).

Here, the parties dispute whether the Parent Application's specification of the doxercalciferol dosage sufficiently enabled a POSA to make and use the compound to lower PTH in patients with secondary hyperparathyroidism without undue experimentation. Insofar as the Court finds that Defendants have shown the existence of a genuine issue of material fact with respect to the written description requirement of § 112, the Court need not reach the question of whether a genuine issue also exists with respect to the enablement requirement.

[9] Defendants point to other aspects of the disclosure in Example 4 that, they argue, indicate dissimilarities with the invention described in Claim 7, including the type of bone disease indicated, type of bone density measurement tests used, and the doxercalciferol dosage specified. The parties may explore those aspects of the case as well at trial.

B. Attorneys' Fees

In Counterclaim IX, Defendants seek attorneys' fees pursuant to 35 U.S.C. § 285, on the ground that Plaintiffs engaged in litigation misconduct by arguing that Claim 7 of the '116 Patent is entitled to a 1988 priority filing date. Plaintiffs argue that, irrespective of whether the '116 Patent is entitled to the 1988 priority filing date of the Parent Application or the 1995 filing date of the '488 Application, Defendants cannot show that they are entitled to attorneys' fees.

Under 35 U.S.C.§ 285, a district court may exercise its discretion to award attorneys' fees to the prevailing party in a patent dispute upon clear and convincing evidence that the case is an "exceptional" one. A case is exceptional when the losing party has conducted the litigation in bad faith or was grossly negligent in conducting the litigation, and when it would be "grossly unjust" for the prevailing party to bear its fees alone. *Abbott Lab. v. Tosoh Corp.*, 1998 WL 173297, at *7-*8 (N.D. Ill. Apr. 8, 1998); *Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1582 (Fed. Cir. 1985).

Plaintiffs argue that, because the '116 Patent is entitled to benefit of the 1988 priority filing date, claiming the benefit of that date cannot be the result of bad faith or gross negligence, and thus will not support an award of attorneys' fees under the statute. Defendants respond that they will present evidence at trial showing that this is an exceptional case warranting an award of attorneys' fees. In light of the Court's decision to deny summary judgment on Affirmative Defenses F and G and proceed to trial on the issue of whether the '116 Patent is in fact entitled to the benefit of the priority date, it would be premature at this juncture to decide whether Plaintiffs have engaged in the type of bad faith or gross negligence as to warrant an award of attorneys' fees to Defendants. The Court therefore denies Plaintiffs motion for summary judgment on Counterclaim IX.

IV. Conclusion

For the reasons stated above, Plaintiffs' motion for summary judgment [336] on Affirmative Defenses F and G and Counterclaim IX is denied.

Dated: September 17, 2010

Robert M. Dow, Jr.
United States District Judge