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. 5,602,116 (the "'116 patent"). On March 31, 2010, the Court held a tutorial and claim construction hearing, at which time it heard evidence and argument regarding the construction of various claim terms in the '116 patent. The claim construction issues also have been extensively briefed. Currently before the Court are Plaintiffs' Opening Claim Construction Brief [224], Defendants' Claim Construction Brief [229], Plaintiffs' Reply Claim Construction Brief [236], and Defendants' Surreply Claim Construction Brief [311]. The Court's construction of the disputed claim is set forth below.

I. Background

The '116 patent, entitled "Method for Treating and Preventing Secondary Hyperparathyroidism," describes a method for preventing loss of bone mass or bone mineral content in persons suffering from secondary hyperparathyroidism using certain vitamin D

analogs. In particular, the claimed invention relates to the treatment of patients having hyperparathyroidism secondary to end-stage renal disease ("ESRD"), a condition which results in a loss of bone mass. Claim 7 of the '116 patent – the only that claim the parties have asked the Court to construe – is directed to a method for the treatment of such patients using 1α-OH-vitamin D_2 (which reads: one-alpha-hydroxy-vitamin D two).

Active vitamin D is essential to maintaining normal calcium and phosphorous levels in the body. In healthy people, vitamin D is activated in the kidney. When a healthy individual's calcium levels fall below normal, the parathyroid glands secrete parathyroid hormone ("PTH"), which causes two things to happen to restore the proper balance. First, PTH signals the bones to release calcium into the blood. Second, PTH signals the kidney to produce active vitamin D, which in turn signals the intestine to absorb more calcium into the blood. ESRD patients' kidneys are not able to produce sufficient active vitamin D. When a person with ESRD has low calcium levels, the kidneys cannot help to restore the balance. As a result, PTH secretion increases (a condition known as "hyperparathyroidism") and the bones release too much calcium, which leads to a loss of bone mass. The '116 patent "provides a method for treating or preventing hyperparathyroidism secondary to end stage renal disease by lowering (or maintaining low) serum parathyroid hormone levels in a patient suffering from the disease." '116 patent, col. 3, ll. 46-50.

II. Legal Standard

In a patent infringement case, the court must engage in a two step analysis. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court determines the meaning and scope of the asserted patent claims. *Id.* Second, the court concludes whether the accused product or device infringes on the properly

construed claims. *Id.* The first step – claim construction – is a legal determination to be made by the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). The Federal Circuit has explained that "'[t]he construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims.'" *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1382 (Fed. Cir. 2005).

Claims must be construed through the eyes of "the person of ordinary skill in the field of the invention." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998); see also *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation."). With that mindset, courts "look to the intrinsic evidence, including the claim language, written description, and prosecution history, as well as to extrinsic evidence" in construing claims. *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1369 (Fed. Cir. 2008).

The Federal Circuit has directed courts to "look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The analysis begins with the words of the claims themselves, which generally are given their ordinary and customary meaning. *Id.* "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313.

The second place to which a court looks in construing claims is the specification, in part to determine whether the inventor has redefined any claim terms. *Vitronics*, 90 F.3d at 1582. The Federal Circuit has explained that, because claims "are part of 'a fully integrated written

instrument,' * * * [they] 'must be read in view of the specification[] of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978-79). Therefore, "the specification is always highly relevant to the claim construction analysis." *Vitronics*, 90 F.3d at 1582. Indeed, the Federal Circuit has advised that the specification "is the single best guide to the meaning of a disputed term," and, therefore, "[u]sually, it is dispositive." *Id.*

Nevertheless, while "the claim language must be examined in light of the written description," the Federal Circuit repeatedly has admonished courts not to read "limitations * * * into the claims from the written description." *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003). In the same vein, the Federal Circuit "has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification." *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). The line between reading a claim in light of the specification, and reading limitations into the claim from the specification is a fine one. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). To "discern[that line] with reasonable certainty and predictability[,] * * * the court's focus [must] remain[] on understanding how a person of ordinary skill in the art would understand the claim terms." *Phillips*, 415 F.3d at 1323.

The third type of intrinsic evidence that the Court may consider, if it is available, is the prosecution history. *Phillips*, 415 F.3d at 1323. However, the Federal Circuit has recognized that, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1317.

If, after reviewing the intrinsic evidence, ambiguity remains regarding the meaning of disputed claim terms, the court may consider extrinsic evidence, including dictionaries, treatises,

and expert testimony. *Phillips*, 415 F.3d at 1317; see also *Vitronics*, 90 F.3d at 1584 ("[o]nly if there [is] still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court * * * resort[] to extrinsic evidence"). However, extrinsic evidence generally is considered to be "less reliable" than intrinsic evidence and "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1318-19.

III. Discussion

The sole claim that the parties have asked this Court to construe is claim 7, which provides:

> 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 D_2 to lower and maintain lowered serum parathyroid hormone levels.[1]

The parties offer conflicting constructions of five claim terms: (i) "lowering or maintaining lowered serum parathyroid hormone;" (ii) "in human patients suffering from;" (iii) "hyperparathyroidism;" (iv) "end stage renal disease;" and (v) "an effective amount of 1α-OH-vitamin D_2 to lower and maintain lowered serum parathyroid hormone levels." The parties also dispute the proper definition of a person of ordinary skill in the art ("POSA") for purposes of the '116 patent.

A. POSA

The parties offer relatively similar characterizations of a POSA. Plaintiffs define a POSA as a person working in the field of kidney diseases and, specifically, someone with a medical degree who was Board certified in nephrology or endocrinology; *or* someone having a Ph.D. in

[1] In its original form, claim 7 states: "The method of claim 2, wherein said analog is 1α-OH-vitamin D_2." Claim 2 in turn reads: "The method according to claim 1, wherein said analog of formula (I) is 1α-OH-vitamin D_2; 1α-OH-vitamin D_4; or 1α,24(R)-(OH)2-vitamin D_4." The parties agree, however, that claim 7 can be redrafted as set forth above to incorporate the limitations of both claims 1 and 2.

biochemistry and at least two years of experience in the field of vitamin D drug discovery. Defendants define a POSA along the same lines, except that they contend that a POSA is someone with both a medical degree *and* a Ph.D. During the claim construction hearing, counsel for both sides indicated that their disagreement regarding the definition of a POSA should not affect the Court's claim construction decision, in that each party maintains that their construction is correct regardless of which definition of a POSA the Court ultimately employs. Therefore, the Court need not determine at this stage whether a POSA must possess both a medical degree and a Ph.D. For purposes of claim construction, the Court will employ the lower of the two proposed thresholds, and will define a POSA as a person working in the field of kidney diseases who either possesses a medical degree and was Board certified in nephrology or endocrinology, or possesses a Ph.D. in biochemistry and has at least two years of experience in the field of vitamin D drug discovery.

B. Lowering or Maintaining Lowered Serum Parathyroid Hormone

Defendants contend that the phrase "lowering or maintaining lowered serum parathyroid hormone" is sufficiently straightforward, and need not be construed by the Court. Plaintiffs propose construing the phrase as "reducing elevated blood concentrations of parathyroid hormone (PTH) or maintaining blood concentrations of PTH at reduced levels." Plaintiffs' proposed claim construction does three things: (1) it replaces "lowering" and "lowered" with "reducing" and "reduced;" (2) it replaces "serum parathyroid hormone" with "blood concentrations of parathyroid hormone"; and (3) it adds that the reduction pertains to *elevated* concentrations of PTH.

With respect to Plaintiffs' first two proposals, the parties agree that Plaintiffs' substituted terms are synonyms for the claim terms (*i.e.*, that "lower" and "reduce" are synonymous, and

that "serum parathyroid hormone" and "blood concentrations of parathyroid hormone" are synonymous). They simply debate the usefulness of Plaintiffs' proposed substitutions.

The Court declines to construe the terms "lowering" and "lowered." The Federal Circuit has recognized that "district courts are not (and should not be) required to construe *every* limitation present in a patent's asserted claims." *O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008); see also *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001) (finding no error in refusal to construe claim term); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1380 (Fed. Cir. 2001) (finding no error in court's refusal to construe "irrigating" and "frictional heat"). The purpose of claim construction is to resolve "disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Where the construction of a claim term does nothing to clarify or explain the patentee's invention, the court is under no obligation to construe the claim. See *id.* (claim construction "is not an obligatory exercise in redundancy"). The Court recognizes that "[w]hen the parties present a fundamental dispute regarding the scope of a claim term," it has a "duty to resolve it." *O2 Micro Intern. Ltd.*, 521 F.3d at 1362. But here Plaintiffs do not contend that construing "lowering" and "lowered" as "reducing" and "reduced" affects the scope of the claim. As they are used in claim 7, the words lowering and lowered – two commonplace terms – are not ambiguous; their ordinary meaning applies. Therefore, the Court will not construe the terms lowering and lowered. See *Biotec Biologische*, 249 F.3d at 1349 (finding no error in court's refusal to construe "melting" where its "ordinary meaning" applied).

By contrast, the Court finds that the second component of Plaintiffs' proposed construction – namely, the substitution of the phrase "serum parathyroid hormone" with the phrase "blood concentrations of parathyroid hormone" – does help to clarify the patentee's claim. The ordinary meaning of the phrase "serum parathyroid hormone" is not immediately apparent to the Court. Plaintiffs' proposed construction – the accuracy of which Defendants do not challenge – clarifies that "serum parathyroid hormone" refers to the concentration of parathyroid hormone in the blood. The construction of "serum parathyroid hormone" as "blood concentrations of parathyroid hormone" also is consistent with the '116 patent specification. See '116 patent, col. 4, lines 57-60 ("the present invention relates to therapeutic methods for lowering the excessively high blood levels of parathyroid hormone (PTH) which are secondary to end stage renal disease"). Therefore, the Court construes "serum parathyroid hormone" as "blood concentrations of parathyroid hormone."

Finally, the parties dispute whether claim 7 should be construed as stating a method for treating patients with "elevated" PTH levels or "substantially elevated" PTH levels. The specification appears to support each proposed construction, as it refers to both "elevated" and "excessively high levels of" PTH. See '116 patent, col. 5, ll. 1-7 ("In accordance with the invention, it has been found that when the analogs of formula (I) are administered to end stage renal disease patients with *elevated serum parathyroid hormone*, PTH concentration is lowered") (emphasis added); *id.*, col. 4, ll. 57-60 ("the present invention relates to therapeutic methods for lowering the *excessively high blood levels of parathyroid hormone* (PTH) which are secondary to end stage renal disease") (emphasis added).

Patent claims are not to be "read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or

restriction." *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1289 (Fed. Cir. 2005) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotations and citation omitted)). Here, the language of the specification evinces no clear intention to limit the scope of the claim to the treatment of patients with *substantially* elevated levels of PTH. Thus, the Court construes claim 7 as claiming a method for treating patients with "elevated" PTH levels.

In sum, the Court construes the phrase "lowering or maintaining lowered serum parathyroid hormone" as "lowering elevated blood concentrations of parathyroid hormone ("PTH") or maintaining lowered blood concentrations of PTH."

C. Suffering From

Plaintiffs' contend that the plain and ordinary meaning of the phrase "suffering from" is "having," and that the claim should be construed as such. Defendants counter that "suffering from" should be construed as "with symptoms of." While, as Defendants note, the specification discusses symptoms associated with hyperparathyroidism, there is no indication that the method described in claim 7 is intended to be limited to treating patients displaying those symptoms. See '116 patent, col. 2, ll. 57-63 ("hyperparathyroidism leads to markedly increased bone turnover and its sequela of renal osteodystrophy, which may include a variety of other diseases, such as osteitis fibrosa cystica, osteomalacia, osteoporosis, extraskeletal calcifcation, and related disorders, e.g. bone pain, periarticular inflammation, and Mockersberg sclerosis").

The Federal Circuit has held that, although dictionaries are extrinsic evidence, they "are often useful to assist in understanding the commonly understood meaning of words" and that consequently "judges are free to * * * 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" *Phillips*, 415 F.3d at 1322-23 (quoting

Vitronics, 90 F.3d at 1584 n.6). Here, the dictionary definition and accompanying commentary regarding the term "to suffer" is helpful in construing the disputed claim term. The American Heritage Dictionary notes that "[i]n medical usage, *suffer with* is sometimes employed with reference to the pain or discomfort caused by a condition, while *suffer from* is used more broadly in reference to a condition, such as anemia, that is detrimental but not necessarily painful." The American Heritage Dictionary, 4th Ed., 2000, p. 1730, usage note. This definition supports the Plaintiffs' proposed construction, suggesting that "suffering from" refers to the existence of a medical condition, not the symptoms associated with that condition. Accordingly, the Court construes "suffering from" as "having."

D. Hyperparathyroidism

Plaintiffs contend that the term "hyperparathyroidism" should be construed as "increased (*i.e.*, above normal) secretion of PTH by the parathyroid gland." Defendants object to Plaintiffs' use of the term "secretion." According to Defendants, the increased PTH levels in patients with hyperparathyroidism secondary to ESRD are caused by more than increased PTH secretion by the parathyroid glands. Therefore, Defendants propose construing the claim term "hyperparathyroidism" as "substantially elevated serum PTH."[2]

Plaintiffs' proposed construction is consistent with the '116 patent specification, which explains that "[r]educed serum levels of 1α,25-$(OH)_2$D cause increased, and ultimately excessive, secretion of PTH by direct and indirect mechanisms," which in turn results in "hyperparathyroidism." '116 patent, col. 2, ll. 55-57. Plaintiffs' construction also finds support in a scientific dictionary. The Oxford Companion to Medicine (Oxford: 1986) defines "hyperparathyroidism" as "increased activity of the parathyroid glands," and states that

[2] As noted above, the Court declines to construe claim 7 as limited to patients with *substantially* elevated serum PTH.

"[s]econdary hyperparathyroidism occurs in response to conditions like vitamin D deficiency and chronic renal disease which tend to depress serum calcium levels." The Federal Circuit has approved the use of "dictionaries, and especially technical dictionaries," by "court[s] in determining the meaning of particular terminology to those of skill in the art of the invention" where "the court deems it helpful in determining 'the true meaning of language used in the patent claims.'" *Phillips*, 415 F.3d at 1318 (citation omitted).

Defendants do not appear to dispute Plaintiffs' position that the term "hyperparathyroidism" refers to increased secretion by the parathyroid glands. Indeed, Defendants' own experts testified that the term "hyperparathyroidism" refers to increased secretion of PTH by the parathyroid glands. See Deftos CC Decl., Exh. F, ¶ 5 ("substantially elevated levels of PTH in the blood of patients with hyperparathyroidism secondary to end stage renal disease ('ESRD') are due not only to *the increased secretion of PTH by the parathyroid glands (the secondary hyperparathyroidism)*, but also to the accumulation of fragments of PTH because of their decreasing excretion by the ailing kidney") (emphasis added); Deftos expert report, Exh. C, ¶ 30 (explaining that secondary hyperparathyroidism occurs where "blood calcium is low and signals the parathyroid gland to produce more PTH"); Segre expert report, Exh. B, ¶ 37 (defining secondary hyperparathyroidism as occurring where "the parathyroid glands secrete excessive amounts of PTH because of extrinsic factors"). Rather, Defendants' point is that other factors also contribute to the increased PTH levels in patients with hyperparathyroidism secondary to ESRD. See Segre CC Decl., Exh. 0, ¶¶ 2-3 ("the increased serum PTH concentrations in ESRD patients with secondary hyperparathyroidism are not simply the result of increased secretions from the PTH glands, but also result from reduced clearance of PTH and PTH fragments from serum"). But the Court's task is to construe the term

"hyperparathyroidism secondary to ESRD," not to describe all of the causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD. Nor does Plaintiffs' proposed construction purport to describe all of those causes. Therefore, Plaintiffs' proposed construction is not inconsistent with Defendants' observation regarding the additional causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD.

The Court sees no need to address the other causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD. Therefore, it construes "hyperparathyroidism" as "increased (*i.e.*, above normal) secretion of PTH by the parathyroid gland."

E. End Stage Renal Disease

Plaintiffs contend that "end stage renal disease" should be construed as "a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation." Defendants counter that the appropriate construction of "end stage renal disease" is "renal impairment which is irreversible and permanent and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life." The parties' constructions present two disputes: (1) whether the dialysis required by patients with ESRD should be described as "chronic"; and (2) whether the dialysis or kidney transplantation required by patients with ESRD should be described as necessary to "ameliorate uremic symptoms."

1. Chronic Dialysis

Plaintiffs' proposed description of the required dialysis as "chronic" is consistent with the patent specification. See '116 patent, col. 11, ll. 43-44 (referring to "men and women with renal disease who are undergoing chronic hemodialysis"); *id.*, col. 12, ll. 13-14 (describing patients as "undergoing chronic hemodialysis"). A U.S. Department of Health and Human Services report relied on by Defendants also supports Plaintiffs' position that ESRD patients require "chronic"

dialysis. See Health Care Financing Research Report, End Stage Renal Disease 1992, HCFA Pub. No. 03359 (Exh. N to [229]) (defining "ESRD patient" as "[a] person with irreversible and permanent kidney failure," and states that they are eligible for Medicare benefits once a "physician certif[ies] that the individual requires chronic dialysis or kidney transplant to maintain life"). Moreover, Defendants' own proposed construction states that ESRD patients require dialysis (or a transplant) to maintain life, thereby implying that the required dialysis is chronic.

Nevertheless, Defendants object to Plaintiffs' proposed inclusion of the term "chronic." Defendants do not take the position that describing the dialysis required by patients with ESRD as "chronic" would be erroneous. Indeed, Defendants agree that patients with ESRD require regular dialysis (or a kidney transplant) in order to survive. Rather, Defendants contend that the inclusion of the adjective "chronic" is superfluous. The Court disagrees. The inclusion of the term "chronic" results in a fuller, more robust definition that is consistent with the claim language and the specification.

2. Uremic Symptoms

The parties' second dispute regarding the construction of "end stage renal disease" centers on Defendants' proposed inclusion of the phrase "to ameliorate uremic symptoms." Defendants' proposed construction is not based on any intrinsic evidence, but is drawn directly from the U.S. Department of Health and Human Services report referenced above. That report defines "end stage renal disease" as "that stage of renal impairment which is irreversible and permanent and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life." Plaintiffs object to the inclusion of any reference to "uremic symptoms" on the grounds any such reference would improperly exclude patients with hyperparathyroidism secondary to ESRD from the scope of the claim if: (1) they never exhibit such symptoms, or (2)

they did exhibit such symptoms, but as a result of treatment, including treatment according to the claimed method, they stopped exhibiting such symptoms.

The Court finds that the inclusion of a reference to "uremic symptoms" does nothing to clarify the scope of the claim, but risks inviting confusion, as the added terms – "uremic symptoms" – would themselves likely require additional construction. Therefore, the Court declines to include such a reference in the construction of claim 7.

In sum, the Court construes "end stage renal disease" as "a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation."

F. Effective Amount

The mostly hotly disputed claim term is the last one – "effective amount of 1α-OH-vitamin D_2 to lower and maintain lowered serum parathyroid hormone levels." Defendants contend that this phrase needs no construction because its ordinary meaning applies.[3] Plaintiffs propose the following construction: "an amount of 1α-OH-vitamin D_2 (also known as doxercalciferol, 1α-hydroxyergocalciferol, or 1α-vitamin D_2), which, when *chronically administered*, reduces blood concentrations of PTH in a *clinically significant manner* and maintains these clinically significant reductions with *a low incidence of hypercalcemia*." Defendants object to three elements of Plaintiffs' proposed construction: (1) the description of

[3] In their claim construction briefs, Defendants took the position – based on the doctrine of claim differentiation – that "effective amount" should be construed as "a range that is broader than the range set forth in claim 3." However, during the claim construction hearing, Defendants' counsel explained that the "effective amount" "could be any amount." Therefore, it appears that the parties agree – consistent with the patent specification – that the "effective amount" is a dose that will vary patient-to-patient based "on a wide variety of factors," including "the efficacy of the specific compound employed, * * * the age, body weight, general state of health, [and] sex [of the patient], * * * the timing and mode of administration, * * * the rate of excretion, and * * * the medicaments used in combination and the severity of the particular disorder to which the therapy is applied." '116 patent, col. 7, lines 7-14.

the "effective amount" as one that is "chronically administered"; (2) the requirement that PTH levels be reduced in a "clinically significant manner"; and (3) the description of the "effective amount" as one that causes "a low incidence of hypercalcemia." Defendants argue that, in each instance, Plaintiffs are improperly importing limitations from the specification into the claim.

1. Chronically Administered

Plaintiffs contend that in order to *maintain* lowered serum PTH levels, as the claim language requires, medication must be administered regularly over an extended period of time. In other words, lowered PTH levels can only be maintained if the drug is administered regularly, or "chronically." Defendants counter that the addition of the words "chronically administered" is inconsistent with Example 3, which discusses short-term treatment (6 weeks), and with Example 5, which discusses both short term treatment (12 weeks) and allows for the possibility that treatment be suspended in the event that a patient develops marked hypercalcemia or hyperphosphatemia. '116 patent, col. 12, ll. 43-48. According to Defendants, such short-term and periodic treatment cannot be considered "chronic."

Defendants' argument regarding the short term nature of the treatment described in Examples 3 and 5 is not persuasive. Both examples discuss clinical trials, which, by necessity, are short term. However, Defendants' point regarding the suspension of treatment is more compelling.

In response, Plaintiffs concede that, occasionally, when a patient develops hypercalcemia, treatment with doxercalciferol must be suspended until the patient's calcium levels fall. However, according to Plaintiffs, treatment with doxercalciferol results in few incidents of hypercalcemia, such that treatment must be suspended only infrequently. Thus, Plaintiffs' proposed inclusion of the phrase "chronically administered" is related to their proposed inclusion of the phrase "a low incidence of hypercalcemia." In particular, according to Plaintiffs,

doxercalciferol causes fewer incidents of hypercalcemia than prior vitamin D therapies for secondary hyperparathyroidism, which used analogs of vitamin D_3 as opposed to vitamin D_2. Consequently, treatment with doxercalciferol will need to be suspended much less frequently than treatment with conventional therapies, making it possible to maintain lowered serum PTH levels.

The word "chronic" means "continuing indefinitely; perpetual; constant." WEBSTER'S NEW WORLD COLLEGE DICTIONARY 262 (4th ed. 2007). Plaintiffs' concession that the claimed invention at times requires the suspension of treatment with doxercalciferol – regardless of how frequently (or infrequently) those incidents may occur – undermines Plaintiffs' contention that claim 7 calls for chronic, or constant, administration. Therefore, the Court declines to construe claim 7 as requiring chronic administration.

2. Clinically Significant Manner

Plaintiffs maintain that a POSA would understand an "effective" treatment to be one that reduces PTH levels in a clinically significant manner (*i.e.*, a manner that benefits the patient). According to Plaintiffs, an amount that reduces PTH levels only nominally cannot be considered "effective," and therefore Defendants' construction – which would encompass amounts that lead to any reduction no matter how insignificant – reads the term "effective" out of the claim. But Plaintiffs provide no guidance as to what "clinically significant" means in this context, or what amount of reduction in PTH levels would be beneficial to a patient. Without such guidance, Plaintiffs' proposal does not clarify the scope of the claim. Rather, by adding a phrase that is vague on its face, it invites confusion. Moreover, the Court finds that the claim term "effective" is not ambiguous in the context of claim 7. Therefore, the Court declines to limit the scope of claim 7 to amounts of 1α-OH-vitamin D_2 that produce "clinically significant" reductions in PTH levels.

3. Low Incidence of Hypercalcemia

Finally, Plaintiffs contend that the scope of claim 7 should be limited to methods that result in a "low incidence of hypercalcemia." It is axiomatic that, because "the claims define the scope of the right to exclude[,] the claim construction inquiry * * * begins and ends in all cases with the actual words of the claim." *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998)). And there is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Here, claim 7 does not explicitly recite a "low incidence of hypercalcemia" limitation, nor is that phrase included in the "ordinary and customary meaning" of the claim term "effective."

However, because claims must be read in light of the specification of which they are a part, the Federal Circuit has recognized that in some instances the ordinary meaning of a claim term may be narrowed by the specification. See *Teleflex, Inc.*, 299 F.3d at 1325 ("The specification may limit the scope of the claims"); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882, 56 USPQ2d 1836, 1839 (Fed. Cir. 2000) ("One purpose for examining the specification is to determine if the patentee has limited the scope of the claims."). In particular, the specification will be found to restrict the scope of the claims if "the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by * * * characterizing the invention in the intrinsic record using words or expressions of *manifest exclusion or restriction*, representing a *clear disavowal* of claim scope." *Teleflex*, 299 F.3d at 1327 (emphasis added).

For example, "where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

See also *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc*., 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."). However, courts must be mindful not to impermissibly import limitations from the specification. *Id.* In *Alloc,* the Federal Circuit offered guidance to district courts seeking to achieve the proper balance between interpreting claims in light of the specification, and avoiding incorporating limitations only found in the specification. According to the *Alloc* court, that balance "turns on how the specification characterizes the claimed invention." *Id.* The court further explained that courts should "look[] to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment." *Id.*

Applying that standard, the *Alloc* court concluded that the "specification read as a whole [led] to the inescapable conclusion that the claimed invention must include play in every embodiment," and held that the disputed claims included a "play" limitation, despite the fact that the claims did not recite a "play" limitation. *Id.* In reaching that conclusion, the court was persuaded by the following: (i) the "specification criticize[d] prior art floor systems without play," (ii) "all the figures and embodiments disclosed in the asserted patents impl[ied] * * * [or] expressly disclose[d] play," and (iii) "the patents d[id] not show or suggest any systems without play." 342 F.3d at 1369-70. While the court found that "the specification alone [was] sufficiently clear," it noted that "the prosecution history of [the] patent family confirm[ed] the

description in the specification of each patent, namely, that play is a key feature of the claimed invention." *Id.* at 1371.

Similarly, in *SciMed*, the court found that the specification limited the scope of the asserted claims to catheters with coaxial lumens, and disclaimed catheters with dual lumen configuration, despite the absence of such limiting claim language. For that conclusion, the court relied on statements in the specification identifying the inflation lumen as coaxial rather than dual in structure, including numerous statements characterizing "the coaxial configuration as part of the 'present invention.'" 242 F.3d at 1342-43. The court also was persuaded by statements in the specification "distinguish[ing] the prior art on the basis of the use of dual lumens and point[ing] out the advantages of the coaxial lumens used in the catheters that [were] the subjects of the SciMed patents." *Id.* at 1343. Finally, the court noted that the specification expressly identified the coaxial lumen configuration as "the basic sleeve structure for *all embodiments of the present invention contemplated and disclosed herein*." *Id.* (emphasis in original).

The specification, in conjunction with the patent prosecution history, also was found to limit claim terms in *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307 (Fed. Cir. 2007), on which Plaintiffs rely. In *Ormco*, the Federal Circuit concluded that the asserted claims required automatic computer control of the finish tooth positioning, despite the fact that the claim language did not expressly recite such a limitation. The court was persuaded, in part, by statements in the specification distinguishing the invention based on "its high level of automation in the design of custom orthodontic appliances as compared to the prior art," and "specifically stat[ing] that the prior art had encountered difficulties in 'the task of developing an *automated* system that includes reliable and efficient *decision making algorithms* and techniques *for*

automatically determining an ideal finish position of the teeth.'" 498 F.3d at 1313 (emphasis in original). The court also relied on the fact that the specification did not "suggest or even allow for human adjustment of the computer-calculated tooth finish positions." *Id.* The court noted that "all those statements by the inventors in the specification of the Ormco patents, standing alone, may not be conclusive in showing that the claims require completely automatic determination of final tooth positions," but found that "statements made during prosecution in order to overcome a rejection over prior art" confirmed the conclusion. *Id.* at 1316.

In light of the foregoing discussion, the question presented to this Court in the parties' briefs is whether the specification compels the conclusion that claim 7 includes a hypercalcemia limitation. Plaintiffs contend that the specification indicates that the patentee intended to limit the scope of claim 7 to amounts of doxercalciferol that result in a "low incidence of hypercalcemia." In support of that contention, Plaintiffs note that the specification describes "the present invention" as having lower toxicity (*i.e.*, less resultant hypercalcemia and hyperphosphatemia) than conventional therapies using vitamin D_3 compounds. See '116 patent, col. 4, ll. 11-17 ("SUMMARY OF THE INVENTION" section stating that "[t]he treatment method of the present invention is * * * characterized by providing an active vitamin D compound having equivalent bioactivity [to conventional therapy with vitamin D_3 compounds] but much lower toxicity than these conventional therapies."); *id.*, col. 4, ll. 60-62 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia"); *id.*, col. 13, ll. 57-59 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia."). Statements in the specification describing a particular feature as part of the "present invention" can be "strong evidence" that the claims should be read to require that feature. *SciMed*, 242 F.3d at

1343. See also *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (construing claim term to be limited to a fuel filter where "[o]n at least four occasions, the written description refer[red] to the fuel filter as 'this invention' or 'the present invention'").

Statements in the '116 patent specification criticizing the prior art (*i.e.*, conventional therapies using vitamin D_3 compounds) for causing toxicity in the form of hypercalcemia and hyperphosphatemia, and touting the claimed invention as a solution to those toxicity problems, provide additional support for a narrowing construction along the lines suggested by Plaintiffs. See '116 patent, col. 2, ll. 6-9 ("at the dosage ranges required for [vitamin D_3 compounds] to be truly effective, toxicity in the form of hypercalcemia and hypercalciuria becomes a major problem"); *id.*, col. 2, ll. 26-29 ("the prior art teaches that due to their toxicity, 1-hydroxylated vitamin D compounds can only be administered at dosages that are, at best, modestly beneficial in preventing or treating loss of bone or bone mineral content"); *id.*, col. 3, ll. 5-7, 14-15 (1α,25-$(OH)_2D_3$ and 1α-OH-D_3 often cause "toxic side effects (hypercalcemia and hyperphosphatemia)" at certain dosages); *id.*, col. 3, ll. 35-41 (despite the "known problems with use of the hormonally active vitamin D_3 for secondary hyperparathyroidism, the art has not adequately responded to date with the introduction of other vitamin compounds, derivatives or analogs that possess less inherent toxicity"); *id.*, col. 5, ll. 1-9 ("In accordance with the invention, it has been found that when the analogs of formula (I) are administered * * *, PTH concentration is lowered with significantly less hypercalcemia and hyperphosphatemia than is observed after the same amount of activated vitamin D administered in previously known formulations"); *id.*, col. 5, ll. 30-31 ("The analogs of formula (I) are substantially less toxic than their vitamin D_3 counterparts.").

As a general matter, the Federal Circuit has stated that where "[t]he specification * * * teaches about the problems solved by the claimed invention, the way the claimed invention

solves those problems, and the prior art that relates to the invention[,] * * * [t]hese teachings provide valuable context for the meaning of the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1554 (Fed. Cir. 1997), overruled in part on other grounds by *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998). More specifically, the Federal Circuit repeatedly has found that statements criticizing the prior art and distinguishing the invention as a solution to the identified problem may serve to narrow the scope of a claim. See *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharmaceutical Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004) ("Where the general summary or description of the invention describes a feature of the invention * * * and criticizes other products * * * that lack that same feature, this operates as a clear disavowal of these other products"); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (finding that specification's "detailed discussion of the prior art problem addressed by the patented invention * * * further supports the conclusion that * * * the patentee has limited the scope of the '879 patent claims").

Here, a number of statements in the '116 patent specification – describing the invention in terms of lower incidences of hypercalcemia, criticizing the prior art, and distinguishing the claimed invention from the prior art on the basis of lower toxicity – "make[] clear * * * that the claimed invention is narrower than the claim language might imply." *Alloc*, 342 F.3d at 1370. The question is how much narrower. Based on its examination of the language used in the specification, the Court concludes that Plaintiffs' proposed construction – which allows for only a "low incidence of hypercalcemia" – is too narrow.

As noted above, the specification repeatedly refers to the method of the invention as causing "lower toxicity" and "less resultant hypercalcemia" than conventional extant therapies

that used Vitamin D_3 compounds. And in its discussion of the prior art, the specification similarly emphasizes that the invention would lead to "significantly less hypercalcemia" and would be "substantially less toxic" than its Vitamin D_3-based predecessors. These references have as their common focus not a "low" incidence of hypercalcemia in some absolute sense, but rather an incidence of hypercalcemia that is "less" or "lower" than the incidence reported from the prior therapies which used analogs of Vitamin D_3, as opposed to Vitamin D_2. The phrase "low incidence of hypercalcemia" appears nowhere in the specification.

The upshot of this analysis is that while the specification does narrow the claim scope, it does not narrow it as much as Plaintiffs contend. In particular, the specification contains a "clear disavowal" of amounts of doxercalciferol resulting in an incidence of hypercalcemia that is equal to or greater than the incidence of hypercalcemia associated with the then-conventional Vitamin D_3 treatments. See *Teleflex*, 299 F.3d at 1327. But the specification does *not* clearly disavow all amounts of doxercalciferol that cause more than a *low* incidence of hypercalcemia. Thus, claim 7 encompasses amounts of doxercalciferol that result in a *lower* incidence of hypercalcemia relative to previously available therapies, even if a POSA would not consider that relatively lower incidence to be "*low*" in absolute terms. Or, put slightly differently, the specification leads to the "inescapable conclusion" that claim 7 is limited to amounts of doxercalciferol that result in a lower incidence of hypercalcemia than was associated with the conventional Vitamin D_3 treatments in existence at the time of the invention. See *Alloc*, 342 F.3d at 1341.

Defendants maintain that certain portions of the intrinsic evidence – specifically Examples 3 and 5 and the Tan manuscript – do not support the narrow construction Plaintiffs propose. The Court finds all three examples cited by Defendants to be entirely consistent with

the construction set forth above. With respect to Example 5, Defendants point to the fact that the protocol for the clinical trial discussed in the example allows for a dosage reduction for patients who develop persistent mild hypercalcemia or mild hyperphosphatemia during treatment with 1α-OH-vitamin D_2, and calls for patients who develop marked hypercalcemia or hyperphosphatemia to immediately suspend treatment. '116 patent, col. 12, ll. 43-48. Plainly the fact that the protocol for Example 5 allows for the possibility of incidents of hypercalcemia is not inconsistent with the Court's construction, which merely requires a *lower* incidence of hypercalcemia than that observed with traditional Vitamin D_3 therapies, not a complete prevention of hypercalcemia.

The Tan manuscript describes a clinical trial involving the administration of 1α-OH-vitamin D_2 to ESRD patients, and reports 13 instances of hypercalcemia in 24 treated patients. PH001420, PH001423. The Tan manuscript also reports just 4.7 episodes of hypercalcemia per 100 weeks of treatment, and concludes that "[t]he results demonstrate that this vitamin D analog [1α-OH-vitamin D_2] is highly effective in lowering serum [PTH] levels with a very low incidence of hypercalcemia and hyperphosphatemia." Defendants' own expert concedes that a POSA would consider "4.7 episodes of hypercalcemia per 100 weeks of treatment * * * [to] be an acceptable low occurrence of hypercalcemia." Chesnut Dep. at 29. Thus, the Tan manuscript is consistent with the Court's construction, and, in fact, lends support to Plaintiffs' even narrower construction.

Finally, Example 3, which discusses a clinical trial in which five ESRD patients were administered 1α-OH-vitamin D_2 at a dosage of 4 µg/day for six weeks, also is consistent with the Court's construction. In Example 3, three of the five patients "developed mild hypercalcemia (serum calcium, 10.3-11.4) that reversed after stopping 1 α-OH-vitamin D_2." *Id.*, col. 11, ll. 20-

23. Defendants argue that 60% of patients developing hypercalcemia cannot be considered a low incidence, and that Example 3 therefore refutes Plaintiffs' claim that the specification supports a low incidence of hypercalcemia limitation. Presumably, Defendants also would take the position that three of the five patients developing hypercalcemia cannot be considered a "lower" incidence as compared to the prior art. The problem with Defendants' analysis is that it focuses on the absolute number of incidents of hypercalcemia, as opposed to the frequency of those incidents over time. In other words, Defendants fail to put the raw data (*i.e.*, how many patients experience an episode of hypercalcemia) into the proper context (*i.e.*, how often patients experienced hypercalcemia during treatment). But when it comes to the "incidence of hypercalcemia," the pertinent inquiry is the frequency with which patients develop hypercalcemia during extended periods of treatment. As a result of its brevity, Example 3 provides no information regarding how many times the patients described in the example developed hypercalcemia *over time*. Therefore, Example 3 does not undermine the Court's hypercalcemia limitation, which speaks to the frequency with which patients experience hypercalcemia.

Defendants also argue that the inclusion of a limitation addressing the incidence of hypercalcemia but not the incidence of hyperphosphatemia would be improper. Plaintiffs respond that a limitation regarding hyperphosphatemia is not proper because a low incidence of hyperphosphatemia is not central to the functioning of the claimed invention. See *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1351-52 (Fed. Cir. 2004) (concluding that claim term included a limitation that the specification made clear was "central to the functioning of the claimed inventions," but did not include a second limitation that "the specification [did not] indicate [was] necessary for the multiplexing function" of the inventions). As Plaintiffs

note, other drugs – namely phosphate binders – existed to control that side effect. The specification indicates repeatedly that the inventors intended for the claimed method to be used in conjunction with phosphate binders to control hyperphosphatemia. See '116 patent, ex. 3, col. 11, ll. 3-8 ("Throughout the * * * treatment period, patients * * * ingested significant amounts of calcium phosphate binders (1-10 g elemental Ca) to keep serum phosphorus levels below 6.9 mg/dL"); *id.*, ex. 4, col. 11, ll. 53-55 ("Oral calcium phosphate binders are used as necessary to maintain serum levels of phosphorus below 7.0 mg/dL"); *id.*, ex. 5, col. 12, ll. 39-43 ("patients * * * ingest calcium phosphate binders (such as calcium carbonate or calcium acetate) in an amount sufficient to keep serum phosphate controlled"); *id.*, col. 4, ll. 60-64 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia, especially in patients who use oral calcium phosphate binders to control serum phosphorus levels."). The specification therefore indicates that controlling hyperphosphatemia is not an essential function of the claimed method of treatment. Consequently, the Court's construction – which includes a hypercalcemia-related limitation but not a hyperphosphatemia-related limitation – is appropriate.

Finally, the Court considers the prosecution history, which both sides contend supports their respective positions regarding the proposed low incidence of hypercalcemia limitation. U.S. Patent Nos. 5,104,864 (the "'864 patent") and 5,403,831 (the "'831 patent"), which are part of the '116 patent prosecution history, contain claims that are structurally similar to claim 7 in the '116 patent. In that regard, the '864 and '831 patent claims refer only to an "amount" – not an "effective amount" – and expressly require that the "amount" not cause hypercalcemia at all. For example, Claim 1 of the '864 patent states:

> A method for reversing loss of bone mass or bone mineral content in a human being displaying or predisposed to developing osteoporosis, comprising the step

> of: administering to said human being an amount of 1α-hydroxyergocalciferol ($1\alpha OHD_2$) sufficient to reverse loss of bone mass or bone mineral content without causing hypercalciuria or hypercalcemia, said amount being at least 2.0 µg/day."

'864 patent, col. 7, ll. 39-46.[4]

Defendants contend that if the inventors of the '116 patent had intended to require a specific incidence of hypercalcemia in claim 7 – *e.g.*, a "low incidence" or "without causing hypercalcemia [at all]" – they would have said so explicitly, as they did in the earlier related patents. Plaintiffs counter that the similarity between the claims illustrates that the term "effective," as it is used in claim 7 of the '116 patent, is a short-hand reference to the prevalence of side effects such as hypercalcemia.

While the Court finds Plaintiffs' contention to be unconvincing, the import of the omission of an express reference to hypercalcemia is not so clear as to provide useful guidance for purposes of construing claim 7 one way or the other.[5] The Federal Circuit has advised that "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317. Here, the Court is looking at the final product, but the substance of the negotiations that led to

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[4] Similarly, claim 1 of the '831 patent states:

> A method for preventing loss of bone mass or bone mineral content post menopausal women, comprising: administering to said human an amount of 1α-hydroxyl vitamin D_2 [lα-OH-vitamin D_2) sufficient to prevent loss of bone mass or bone mineral content without causing hypercalcemia or hypercalciuria."

'831 patent, col. 8, ll. 5-10.

[5] Parenthetically, the Court observes that even if the Court were to accept Plaintiffs' claim that "effective" is shorthand for "without causing hypercalcemia or hypercalciuria," Plaintiffs' proposed construction does not comport with that argument. In particular, Plaintiffs argue for a "low incidence of hypercalcemia" limitation, not a complete lack of hypercalcemia limitation (which they concede would be inconsistent with the examples in the specification) like the one in the '864 and '831 patents.

the omission – and thus the reasons behind the omission – are not clear. Therefore, the prosecution history does not undercut the Court's conclusion that claim 7 includes a hypercalcemia-related limitation. Here – as is often the case – the specification is "dispositive." *Vitronics*, 90 F.3d at 1582.

In sum, the "specification read as a whole leads to the inescapable conclusion that" claim 7 is limited to amounts of doxercalciferol that result in a lower incidence of hypercalcemia than was associated with the conventional Vitamin D_3 treatments in existence at the time of the invention. See *Alloc*, 342 F.3d at 1341. As described above, "the specification makes clear that the invention does not include" amounts of doxercalciferol resulting in an incidence of hypercalcemia that is equal to or greater than the incidence of hypercalcemia associated with the then-conventional Vitamin D_3 treatments. *SciMed*, 242 F.3d at 1341. In light of that "clear disavowal of claim scope" (*Teleflex*, 299 F.3d at 1327), the Court construes the final disputed claim term as follows: "an effective amount of 1α-OH-vitamin D_2 to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than is associated with the extant conventional Vitamin D_3 treatments."

IV. Conclusion

For the foregoing reasons, the Court construes claim 7 of the '116 patent as follows:

A method for lowering elevated blood concentrations of parathyroid hormone ("PTH") or maintaining lowered blood concentrations of PTH in human patients having increased (*i.e.*, above normal) secretion of PTH by the parathyroid gland as a result of a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation, comprising: administering an effective amount of 1α-OH-vitamin D_2 to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than is associated with the extant conventional Vitamin D_3 treatments.

Dated: June 4, 2010

Robert M. Dow, Jr.
United States District Judge