# United States District Court, Northern District of Illinois

| Name of Assigned Judge or Magistrate Judge | Robert M. Dow, Jr | Sitting Judge if Other than Assigned Judge | |
|---|---|---|---|
| CASE NUMBER | 08 C 1083 | DATE | 3/30/2011 |
| CASE TITLE | Bone Care, Int'l et al. vs. Pentech Pharm., et al. | | |

**DOCKET ENTRY TEXT**

Before the Court are Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc.'s (collectively, "Defendants") motion for summary judgment [473] of invalidity of claim 7 of U.S. Patent No. 5,602,116 ("the '116 patent") for lack of enablement and lack of written description, and Plaintiffs Bone Care International, LLC and Genzyme Corporation's (collectively, "Plaintiffs") cross-motion for summary judgment [492] that the '116 paten is enabled as of the filing date of its parent patent application. For the reasons below, the Court denies both motions [473, 492].

■[ For further details see text below.] Docketing to mail notices.

## STATEMENT

### I. Background

The factual and procedural history of this case has been described at length in this Court's numerous previous rulings in this litigation. [See 327, 468, 498, 496.] The Court provides only a brief description of the relevant background here.

The U.S. Patent and Trademark Office issued the '116 patent – entitled "Method for Treating and Preventing Secondary Hyperparathyroidism" – to Plaintiffs on February 11, 1997. The '116 patent issued from the '488 continuation-in-part patent application, which was filed on April 3, 1995. The '488 application was linked through a chain of continuation and continuation-in-part applications to a parent patent application, the '371 application ("the '371 application" or "the parent application"), which was filed on August 2, 1988.

As construed by the Court [see 468], claim 7 of the '116 patent teaches:

> 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 dialysis or kidney transplantation, comprising: administering an amount of 1α-OH-vitamin $D_2$ sufficient to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than would result from using 1α,25-$(OH)_2$ vitamin $D_3$ or 1α-OH vitamin $D_3$ to achieve the same level of PTH suppression.

[468.] In other words, the invention claimed concerns (1) using an amount of doxercalciferol (2) to achieve a

lowered PTH level – (3) which level is the same as that achieved by 1α,25-$(OH)_2$-vitamin $D_3$ ("calcitriol") and 1α-OHD-vitamin $D_3$ ("alfacalcidol") (collectively, "the vitamin $D_3$ compounds") – (4) while causing an incidence of hypercalcemia (a condition characterized by toxically high levels of calcium in the blood) (5) that is less than the incidence of hypercalcemia caused by the vitamin $D_3$ compounds when those compounds are used at effective doses, (6) in patients with hyperparathyroidism secondary to end-stage renal disease ("ESRD patients").

Defendants sought approval from the U.S. Food and Drug Administration to manufacture, use, or sell a generic form of doxercalciferol in a manner covered by claim 7 of the '116 patent. Consequently, Plaintiffs sued Defendants for infringement of claim 7 of the '116 patent. Defendants have asserted counterclaims and affirmative defenses alleging that claim 7 is invalid. Two invalidity theories that Defendants raise are that claim 7 (1) does not enable the invention as required by 35 U.S.C. § 112 and (2) does not provide a written description of the invention as required by § 112. Plaintiffs contend that not only does claim 7 satisfy the § 112 requirements, but its parent application also satisfies those requirements, thus entitling the '116 patent to claim the August 2, 1988, filing date of the parent application under 35 U.S.C. § 120.

## II. Discussion

The summary judgment motions currently before the Court relating to the '116 patent [473, 492] were filed less than two months before the commencement of a bench trial that began on October 5, 2010, and concluded on November 4, 2010. Because the motions were not fully briefed until September 24, 2010, the Court was unable to consider them before trial.

At trial, the Court heard testimony from numerous fact and expert witnesses over 12 trial days. That testimony touched on a wide range of issues, including the enablement and written description issues on which the pending summary judgment motions focus. After the trial concluded, the Court set a schedule for post-trial memoranda and gave the parties leave to file oversized briefs of up to 280 pages per side. [See 573.] The docket reflects that the last of those briefs [638, 639] were filed on February 18, 2011.

Turning to the disposition of the instant motions, the Court first has considered whether the issues relating to enablement and written description can be resolved on the basis of the summary judgment record alone – that is, without any need to consider the testimony at trial as it relates to those issues. After careful consideration of the briefs and the Local Rule 56.1 materials submitted by the parties, the Court concludes that, when "construing the facts and drawing all reasonable inferences in the light most favorable to the nonmoving party" (see *Foley v. City of Lafayette*, 359 F.3d 925, 928 (7th Cir. 2004)), genuine issues of material fact preclude disposition on summary judgment for either side. Because the Court will comprehensively address the enablement and written description claims in what will certainly be a lengthy written opinion, the Court will not discuss in detail in this opinion either the legal framework of those claims or the application of the summary judgment record to that framework. Nevertheless, the Court will provide a "bottom line" assessment of why it has concluded that summary judgment is not appropriate on the issues briefed by the parties in their respective motions.

To begin with, the Court's review of the record on summary judgment indicates that there is no decisive victor in the battle of the experts on the enablement question. Plaintiffs acknowledge that their own experts "disagree that the POSA would have had a reasonable expectation, based solely on the prior art, that doxercalciferol was capable of lowering and maintaining lowered PTH levels with a lower incidence of hypercalcemia than associated with the prior art while achieving the same level of PTH suppression." [487, at 20 n.16.] It is facially evident that the specification of claim 7 does not disclose the dose at which doxercalciferol should be administered to achieve a target PTH level or that the doses at which the vitamin $D_3$ compounds are administered

achieve those same target PTH levels, nor does the specification disclose data on the relative incidence of hypercalcemia in ESRD patients administered either drug. However, viewing the evidence in the light most favorable to Plaintiffs, a trier of fact reasonably could find that the vitamin $D_3$ compound dosing regimen and associated incidences of hypercalcemia were well enough known that a POSA in 1995 would have been enabled to use or practice the invention claimed without undue experimentation. As such, the Court concludes that there is a genuine factual issue regarding whether claim 7 satisfies the § 112 enablement requirement, and denies Defendants' motion for summary judgment [473] that claim 7 is non-enabling.

In its previous ruling [498], the Court denied Plaintiffs' motion for summary judgment that the '371 parent application satisfied the written description requirement of § 112 (so allowing the '116 patent to claim the benefit of the '371 application's earlier filing date under § 120) after concluding that a genuine issue of material fact existed as to whether a POSA in 1988 reading the disclosure of the '371 application would understand it to describe the same invention later set forth in claim 7 of the '116 patent. In so ruling, the Court noted that the parties' experts disagreed on whether a POSA would understand that the patients described in identical provisions of the '371 application and the '116 patent could be presumed to have secondary hyperparathyroidism. The parties have presented no additional evidence with the current motions that dispels the enduring doubt as to this question. Because expert opinion differs on the issue, and for the same, though converse, reasons as those noted in the Court's [498] ruling as to the '371 application, a trier of fact reasonably could find that the specification of the '116 patent satisfies the written description requirement of § 112. The Court therefore denies Defendants' summary judgment motion [473].

Plaintiffs in their cross-motion [492] argue that the disclosure of the '371 parent application provides sufficient data to enable the claimed invention as of 1988. Specifically, Plaintiffs argue that Example 1 and Example 4 of the '371 application provide sufficient data for a POSA in 1988 to have used the invention claimed in the '116 patent. That argument likewise cannot carry the day on the basis of the summary judgment record alone.

Example 1 of the '371 application describes an actual clinical trial involving six postmenopausal women who were administered doxercalciferol in doses "up to five micrograms" without significant incidence of hypercalcemia. Plaintiffs state that a POSA reading this specification could have a reasonable expectation that doxercalciferol could be administered at that dosage to treat ESRD patients with lower risk of hypercalcemia than the vitamin $D_3$ compounds. However, as Defendants point out, the women in the clinical trial described in Example 1 were not ESRD patients whose kidneys were, by definition, failing, but rather were likely to have had functioning kidneys. Given that the human body metabolizes calcium in the kidneys, Defendants claim that the data included in Example 1 is not prognostic of the efficacy and safety of doxercalciferol's use in ESRD patients.

Example 4 of the '371 application is essentially identical to Example 4 of the '116 patent. As in Example 4 of the '116 patent, Example 4 of the '371 application does not specify the anticipated dosing levels of doxercalciferol or of the vitamin $D_3$ compounds, nor does it mention the target level of PTH to be achieved in the patient group treated with doxercalciferol. It is unclear on the facts presented whether the effects and risks of treatment with both drugs were well enough known in 1995 – let alone in 1988 – that a POSA could have used the invention in ESRD patients in the manner prescribed without undue experimentation. In view of that ambiguity, Defendants have shown more than a metaphysical doubt that a trier of fact reasonably could find that a POSA would not have been enabled by the '371 application's specification. The Court therefore denies Plaintiffs' cross-motion for summary judgment [492].

## III. Conclusion

For the reasons stated above, the Court respectfully denies both Defendants' motion for summary judgment [473] and Plaintiffs' cross-motion for summary judgment [492] on the § 112 issues raised in those motions and supporting materials. The Court will proceed to a written decision on those and the myriad other issues raised by the parties with the benefit of the voluminous trial record and the parties' post-trial memoranda.