

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	October 4, 2010
CASE TITLE	Bone Care v. Pentech		

DOCKET ENTRY TEXT

This minute order is issued to clarify a matter raised at this morning's status hearing concerning the scope of the Court's *in limine* rulings on Plaintiffs' motion to preclude testimony regarding certain invalidity defenses (Plaintiffs' "fourth" motion *in limine* [409]) and Defendants' motion to preclude Plaintiffs from presenting evidence that purports to show entitlement to a claim of priority under 35 U.S.C. § 112 [399]).

■ [For further details see text below.]

Docketing to mail notices.

STATEMENT

This minute order is issued to clarify a matter raised at this morning's status hearing concerning the scope of the Court's *in limine* rulings on Plaintiffs' motion to preclude testimony regarding certain invalidity defenses (Plaintiffs' "fourth" motion *in limine* [409]) and Defendants' motion to preclude Plaintiffs from presenting evidence that purports to show entitlement to a claim of priority under 35 U.S.C. § 112 [399]). In the Court's ruling of September 30, 2010 [518], Plaintiffs' motion [409] was granted with respect to evidence of indefiniteness and lack of utility and denied with respect to evidence of anticipation, insufficient written description, and nonenablement, and Defendants' motion [399] was denied. As the discussion on the record in open court at this morning's status conference bore out, the parties dispute whether the Court's rulings precluded evidence of the utility aspect of enablement.

Having reviewed the rulings on Plaintiffs' "fourth" motion *in limine* [409] and Defendants' motion *in limine* [399] in light of this morning's discussion and the other relevant rulings in the case, the Court issues the following clarification. In addressing both motions, the Court addressed the Section 101 lack of utility and Section 112 nonenablement defenses separately. See Mem. Op. [518], at 8, 9-10, 14-15. As the Court noted, "the utility and enablement requirements, although related, are nevertheless distinct and cannot be folded into an identical analysis." *Id.* at 14. The Court also observed that "the two requirements are set forth in different sections of patent law – utility in § 101 and enablement in § 112." *Id.* In context, the further statement cautioning Defendants against attempting an "end run" to prove nonenablement by arguing lack of utility (*id.* at 15) was meant to reinforce the exclusion of evidence pertaining to the Section 101 lack of utility defense that had been excluded because of Defendants' "late and scant" assertions as to that defense (*id.* at 10), but was not meant to limit any aspects – including the so-called "utility aspect of enablement" – of an enablement defense under Section 112. The Court thus did not, as Plaintiffs suggest, carve out the "how-to-use" or "utility aspect" of enablement under Section 112 by precluding the Section 101 lack of utility defense.

STATEMENT

Limiting Defendants' enablement case under Plaintiffs' proposed reading of the *in limine* opinion also would be inconsistent with the Court's revised claim construction, in which the Court stated the following:

Nothing in the Court's claim construction forecloses Defendants from arguing (and presenting evidence) that treatment with $1\alpha,25\text{-(OH)}_2$ vitamin D₃ or $1\alpha\text{-OH}$ vitamin D₃ is not associated with high (or higher) incidence of hypercalcemia or that Plaintiffs have no evidence that treatment with $1\alpha\text{-OH}$ -vitamin D₂ results in less hypercalcemia than treatment with the vitamin D₃ compounds. If Defendants are correct as to Plaintiffs' failure of evidence, then the likely result would be that claim 7 is inoperable, not indefinite. See *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1382 (Fed.Cir. 2001) (stating that inoperable embodiments present "an issue of enablement, and not indefiniteness")

[468, at 10 n.4.] The upshot of this analysis is that while a Section 101 utility defense is out of the case, any aspect of a Section 112 nonenablement defense – including the utility aspect of enablement – remains in the case.

That brings to the fore the new study, apparently published on-line on September 22, 2010, that Defendants brought to the Court's attention at this morning's status hearing. The potential relevance of the study – entitled "Calcitriol and doxercalciferol are equivalent in controlling bone turnover, suppressing parathyroid hormone, and increasing fibroblast growth factor-23 in secondary hyperparathyroidism" – is clear, at a minimum with respect to the utility aspect of enablement issue that remains in the case. Because of the potential relevance to that defense and because no party could be expected to have questioned their expert witnesses about a study that was not complete while expert discovery was open, the Court concludes that the parties should be able to examine and cross-examine the expert witnesses on the study at trial. Defendants already have discussed the study with their expert, Dr. Deftos, and have provided to Plaintiffs slides that set forth Dr. Deftos' views on the study. However, given that the study was not known to counsel until late last week and Dr. Deftos' slides were not provided to Plaintiffs until this morning, the Court does not believe that it would be fair to expect counsel for Plaintiffs to cross-examine Dr. Deftos on his opinions as soon as tomorrow or Wednesday, when Defendants propose to call Dr. Deftos in their case-in-chief.

As the parties discussed at this morning's status, there are two possible ways of handling this issue. One option is that Defendants would call Dr. Deftos and elicit his direct testimony on the study along with all of their other direct examination of Dr. Deftos this week, and then make Dr. Deftos available for cross-examination later in Defendants' case-in-chief (during the week of October 19-22, when Plaintiffs' case-in-chief is set to resume). The other option is to take all of Dr. Deftos' testimony (direct and cross) on all subjects except for the study this week, and then take his testimony on the study (direct and cross) during the week of October 19-22.

On balance, and in the exercise of the Court's discretion under Rule 611, the Court concludes that (1) the presentation of evidence will flow more smoothly both for the parties and the Court, (2) the Court's ability to receive the evidence (as the trier of fact) will be more coherent, and (3) the record will be cleaner if all of Dr. Deftos' testimony on the study is taken at the same time. Because of the prejudice concerns raised by Plaintiffs in connection with the need to prepare cross-examination overnight based on the slides that Defendants provided this morning, the Court does not believe that the cross-examination could take place as early as October 5 or 6, which are the scheduled dates for trial this week. And, pursuant to Defendants' proposal, Dr. Deftos will have to be made available sometime during the week of October 19-22 for his cross-examination in any event. Thus, the Court concludes that all examination of Dr. Deftos in Defendants' case-in-chief concerning the new study should take place when Dr. Deftos is recalled during the week of October 19-22.