UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION, ***Plaintiffs,*** **v.** **PENTECH PHARMACEUTICALS, INC.,** ***Defendant.***	)	**Civil Action No.: 08-cv-1083** **Honorable Robert M. Dow Jr.** **Magistrate Judge Martin C. Ashman**

Plaintiffs' Reply Brief Regarding Timing Of Claim Construction

Plaintiffs Bone Care International LLC and Genzyme Corporation (hereinafter collectively "Genzyme" or "Plaintiffs"), reply to Defendant Pentech Pharmaceutical, Inc.'s ("Pentech" or "Defendant") Memorandum Of Law In Support Of Holding Claim Construction Proceedings Concurrently With Discovery ("Pentech's Opening Brief"), filed on May 23, 2008. Pentech asserts early claim construction expedites ANDA cases, and claim construction is achievable without fact discovery. On both counts Pentech is wrong.

The Case Schedule Is Largely Undisputed, And Allows For Resolution Of This Litigation Before The Statutory 30-Month Stay Expires

This case can be resolved prior to the expiration of the 30-month stay under Plaintiffs' proposal that claim construction commence after the completion of fact discovery. Defendant's contention that under its proposed schedule "it is far more probable that this case will be resolved prior to [the] expiration of the 30-month stay, than under Plaintiffs' proposal" is wrong. (*See* Pentech's Opening Br. at 5.) In fact, in the Joint Rule 26(f) Report submitted to this Court on April 21, 2008, the parties agreed to all discovery cut-off dates, including a proposed trial date of April 2010. (*See* Joint Rule 26(f) Report attached hereto as Ex. 1.) The proposed trial date allows for the resolution of this ANDA litigation in advance of July 8, 2010, the expiration of the 30-month stay.[1] Adoption of Plaintiffs' proposal to commence claim construction proceedings

[1] As calculated pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

after the completion of fact discovery in no way jeopardizes the proposed April 2010 trial date. Counsel for both parties agreed to that date knowing the specifics regarding their dispute on the timing of claim construction.

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Regarding Pentech's assertion that claim construction is achievable without fact discovery, Plaintiffs submit that their proposal is reasonable, consistent with judicial trends, including this Court's Standing Order, and maximizes the Court's options regarding the evidence it can consider.

Plaintiffs' Proposal Regarding Timing Of Claim Construction Is Reasonable

Pentech asserts that early claim construction leads to more efficient discovery. In support, Pentech cites David H. Binney & Toussaint L. Myricks, *Patent Claim Interpretation After Markman - How Have The Trial Courts Adapted?*, 38 IDEA 155, 162 (1997) (Pentech Opening Br. at 2, n. 1) (the "Binney Article").

It is instructive to note the Binney Article actually supports Plaintiffs' position and elaborates upon the potential downside to scheduling early claim construction:

> **[I]t may be that the most informed claims interpretation decision would be after the judge has in fact heard all the evidence and understands not only what the parties assert as to the meaning of the claims, but also how those meanings affect the entire case.** In particular, the judge's understanding of the history of the invention and the entire spectrum of prior art will likely be more restricted at an earlier interpretation hearing, both because the parties will limit the evidence they present in this area, and because discovery will not yet have fully developed these subjects.

Id. at 162 (emphasis added).

Moreover, the Binney Article itself notes the range of choices for scheduling claim construction from "very early in the proceedings to after the entire trial." *Id*. In fact, in the *CytoLogix* case cited by Pentech, the court construed claims at the close of trial. *CytoLogix Corp. v. Ventana Med. Sys., Inc*., 424 F.3d 1168, 1170 (Fed. Cir. 2005) ("The district court construed disputed claim terms at the close of trial …")

In any event, the parties' agreed-upon discovery schedule spans twenty-six (26) months from the filing of the Complaint to the proposed trial date. Plaintiffs' proposal that claim construction proceed after the completion of fact discovery is, in fact, at the mid-point of this

schedule, *i.e.*, thirteen (13) months from the filing of the Complaint. Plaintiffs submit that its proposal strikes the right balance between early and truly late (*i.e.*, at the close of trial) claim construction.[2]

Pentech also alleges that early claim construction will streamline discovery and facilitate settlement. (*See* Pentech's Opening Br. at 2.) However, the real world facts simply do not bear that out. In a 2002 survey of the ABA's Intellectual Property Law section, an overwhelming majority (75%) said that claim construction did not effectively cause the parties to limit the scope of discovery from the scope employed before claim construction. *See Claim Interpretation Proceedings and Appellate Review*, Committee No. 601 Subcommittee A, 2002-2003, at 6.[3] Moreover, when asked whether the timing of the *Markman* hearing influenced settlement discussions, there was a perfect split between yes and no. *Id*. at 5.

Judicial Trends Do Not Favor Early Claim Construction

Faced with the fact that the Northern District of Illinois has *not* enacted local rules governing claim construction, Pentech misleadingly argues that several courts have issued local rules "favoring the early disposition of claim construction," to support its assertion that "a judicial trend favors early claim construction." (*See* Pentech's Opening Br. at 3.) In fact, only six (6) districts have enacted such local rules in the twelve years since *Markman v. Westview Instruments* was decided. Six (6) out of eighty-nine (89) judicial districts – 7% – hardly constitutes sufficient support of a "judicial trend."

Moreover, contrary to Pentech's assertion, according to a survey of judges conducted in 2007, claim construction rulings occur most often after discovery, but before trial, thereby allowing the claim construction to "be informed by all information developed through discovery." Rebecca N. Eyre et al., *Patent Claim Construction: A Survey of Federal District*

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[2] Pentech also cites to David G. Herr, *Annotated Manual for Complex Litigation*, § 33.223 (4th ed. 2007) (the "Herr Article") (*See* Pentech's Opening Br. at 2, n. 2) in support of its position for early claim construction. While the Herr Article does state "early *Markman* hearings are preferable to delaying claim construction," Pentech neglects to mention that the delay being referred to is waiting until the close of trial to hold a *Markman* hearing, which is not at all what Plaintiffs propose. *Id.* at 607 ("[E]arly *Markman* hearings are preferable to delaying claim construction **until after the evidence has been heard at trial**." (Emphasis added)).

[3] Pentech's suggestion that early claim construction can limit the scope of discovery translates, as a practical matter, into disputes regarding the scope of discovery that must be resolved by the Court and a corresponding further drain on judicial resources. Furthermore, if discovery is limited, and the Court's construction later reconsidered and changed, there will be a delay in the progress of the case as the omitted discovery is belatedly pursued.

Court Judges, Federal Judicial Center (February 2008).[4] Further, the survey found that "[t]he majority of judges did not use a local rule of their court to manage the claim construction process, apparently preferring to fashion case management orders using other factors, such as their customary practices or their perceptions of the needs of the individual case. Only 21% of the judges (7 of 34) relied on such a local rule, and in all but one of these instances (6 of 7, or 86%) the local rule was specifically designed for patent cases." *Id*. at 12.

By not enacting local rules, the Northern District of Illinois plainly encourages judges to use their discretion to schedule claim construction at a point in the proceedings that best utilizes judicial resources. For the reasons set forth in Plaintiffs' Opening Brief, Plaintiffs submit that their proposed schedule best serves this particular case.

This Court's Standing Order Is Silent On When Claim Construction Proceedings Are To Begin

Pentech cites this Court's March 11, 2008 Standing Order For Patent Claim Construction Proceedings ("Standing Order"), stating that it "follows schedules of other courts' local rules." (*See* Pentech's Opening Br. at 4). Plaintiffs note, however, that the Standing Order does not mandate a particular start time for the claim construction process and the timing set forth applies equally well at any stage of the discovery schedule, including after the completion of fact discovery.

Extrinsic Evidence Serves Multiple Purposes, Including Assisting The Court

Pentech's statement that it is "most likely" that the only evidence relevant to claim construction is that from the intrinsic record proves Plaintiffs' point. (*See* Pentech's Opening Br. at 3.) This Court should have the opportunity to consider extrinsic evidence and not be left to guess whether it will be relevant.

Pentech's assertions that a situation involving genuinely ambiguous claim language after considering the intrinsic evidence is one "which rarely, if ever, occurs," and "litigation-derived inventor testimony" is entitled to "little, if any, probative value," are misplaced. (*See* Pentech's Opening Br. at 2-3) (internal citations and quotations omitted). Plaintiffs' position is simply that claim construction scheduled after the completion of fact discovery will ensure that this Court has the option of receiving all relevant evidence and that any claim construction decision need not be revised in light of factual information discovered thereafter. In other words, whether or

[4] *See* http://www.fjc.gov/public/pdf.nsf/lookup/patclaim.pdf/$file/patclaim.pdf, p. 15.

not this Court finds extrinsic evidence of assistance misses the point – this Court should have the option to receive it.

Finally, Pentech itself acknowledges that extrinsic evidence "may always be consulted … to assist in understanding the underlying technology" and such reliance is "particularly appropriate to ensure that [a judge's] understanding of the technical aspects of the patent are not entirely at variance with the understanding of one skilled in the art." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001) (internal citation and quotations omitted) (cited in Pentech's Opening Br. at 2.)

Conclusion

Plaintiffs maintain that a schedule whereby claim construction proceedings commence after the completion of fact discovery best serves the interest of judicial economy.

Dated: May 30, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2008, a copy of the foregoing **Plaintiffs' Reply Brief Regarding Timing Of Claim Construction** was filed electronically. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system.

/s/ Raven Moore
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