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

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,	
Plaintiffs,	**Civil Action No. 08 C 1083**
v.	**JUDGE DOW** **MAGISTRATE JUDGE ASHMAN**
PENTECH PHARMACEUTICALS, INC.,	**JURY TRIAL DEMANDED**
Defendant.	

PENTECH'S REPLY BRIEF IN SUPPORT OF HOLDING CLAIM CONSTRUCTION PROCEEDINGS CONCURRENTLY WITH DISCOVERY

I. INTRODUCTION

The critical question regarding timing of claim construction is not when it occurs relative to fact discovery, but rather, at what point the record can be sufficiently developed for the parties and the Court to make informed judgments on the meaning of disputed claim terms. Plaintiffs are incorrect that the record can be complete only after the completion of fact discovery. If the Court adopts Defendant's approach to an early claim construction that is officially espoused by several district courts,[1] the parties will have sufficient information to exchange preliminary claim charts by Defendant's proposed date of August 8, 2008.

Much of the fact discovery exchanged is irrelevant to claim construction. It is therefore unnecessary and a waste of time to delay claim construction until after the completion of fact discovery. The better approach is to focus early on discovery regarding matters pertinent only to claim construction, such as is routinely done, for example, in the Northern District of California. This will render the record sufficient for claim construction before completion of fact discovery,

[1] N.D. Cal., N.D. Ga., N.D. Tex., E.D. Tex., W.D. Pa. and S.D. Cal. have local patent rules facilitating early claim construction.

thereby leading to a more speedy and efficient resolution of the case.

II. ARGUMENT

As Plaintiffs concede, "[t]he first and most important source [for construing claims] is intrinsic evidence." Pl. Br. at 4. Intrinsic evidence, *i.e.*, the patent itself and its prosecution history, is available to the parties without discovery.

Plaintiffs are incorrect that fact discovery is needed to procure extrinsic evidence (*e.g.*, dictionaries, treatises and/or expert testimony) that may be used to assist the Court in construing claim terms. *Id.* at 4. To the extent that the parties intend to rely on extrinsic evidence to support their claim interpretations, the parties would obtain such evidence on their own—not wait for the opposing party to produce it during fact discovery. Plaintiffs also are incorrect that they need to finish fact discovery to determine which claims are allegedly infringed. *Id.* at 3. All they need is the ANDA[2] which they will be receiving next month, as explained *infra*.

Plaintiffs' cases (Pl. Br. at 3) do not "endorse" their reasoning regarding the timing of claim construction. In *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996), the court remarked that a trial court deciding a motion for preliminary injunction is not obligated to render conclusive interpretations of patent claim terms, and can wait until the record is more fully developed. This merely follows the well settled principle that substantive decisions at the preliminary injunction stage are not binding at trial. *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990). The issue in *CollegeNet, Inc. v. Applyyourself, Inc.*, 418 F.3d 1225, 1234 (Fed. Cir. 2005) was whether the trial court properly dismissed defendant's patent invalidity counterclaim without prejudice, instead of with prejudice. *Id.* at 1233-34. The plaintiff insisted that defendant's counterclaim should have been

[2] In fact, all Plaintiffs' need to determine potential infringement are small portions of the ANDA; much of the document is irrelevant.

dismissed *with prejudice* because defendant sought dismissal only after presenting its invalidity case. *Id.* at 1234. The Federal Circuit affirmed the dismissal without prejudice because, "the trial court has the discretion to determine whether a party has had an adequate opportunity to present invalidity arguments in the *changing claim construction environment*, and whether a party has acted in a reasonably timely manner in requesting dismissal ... without prejudice." *Id.* (emphasis added). If anything, *CollegeNet* is a prime example of the inefficiency that results from leaving claim construction "in flux" for too long. *See id.*

Plaintiffs incorrectly characterize claim construction after fact discovery as being "consistent with district court practice generally." Pl. Br. at 2. The official trend, as measured by district courts that have enacted local patent rules (*see* n. 1, *supra*), is to conduct claim construction concurrently with fact discovery. There are no local patent rules of any district court in which claim construction is delayed until after the completion of fact discovery.

Defendant's proposed claim construction schedule is akin to schedules set forth in the various local patent rules. Such rules streamline the claim construction process by requiring expeditious exchange of documents and information to develop the record sufficiently for claim construction. Generally, the local patent rules of various courts are modeled after and very similar to the Patent Local Rules of the Northern District of California (N.D. Cal. PLR). The N.D. Cal. PLR are therefore instructive, and should be used as a model, as to how this Court can manage claim construction within the time frame proposed by Defendant.

Under the N.D. Cal. PLR, when a defendant serves invalidity contentions, the defendant simultaneously produces documents sufficient to show the operation of any aspects or elements of an accused product.[3] N.D. Cal. PLR 3-4(a). No more than 10 days after service of invalidity contentions, the parties exchange proposed terms for construction, after which they meet and

[3] In the present case, such documents would consist of Defendant's ANDA No. 90-040.

confer for purposes of limiting the terms in dispute by narrowing or resolving differences. N.D. Cal. PLR 4-1. No more than 20 days after exchanging proposed terms for construction, the parties exchange preliminary claim constructions for each term identified by each party. N.D. Cal. PLR 4-2(a). In this exchange,

> each party shall also identify all references from the specification or prosecution history that support its proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art, and testimony of percipient and expert witnesses. ... With respect to any supporting witness, percipient or expert, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction. N.D. Cal. PLR 4-2(b).

By following the approach of the N.D. Cal. PLR, Plaintiffs will have the documents necessary to understand the accused product (and thus determine which claims allegedly read on the product) well in advance of the exchange of claim construction charts. Moreover, the parties will have had the opportunity to determine and exchange any evidence (intrinsic or extrinsic) they will use to support their respective claim constructions, months in advance of the completion of fact discovery. Plaintiffs' concern that Defendant's proposed schedule will not render a record sufficient for claim construction is therefore obviated.[4] Plaintiffs' cases (Pl. Br. at 2-3) expressing a preference for delaying claim construction until after fact discovery do not follow an expedited schedule such as that set forth in the N.D. Cal. PLR. Those cases are therefore inapposite if the Court adopts Defendant's proposed schedule.

If Plaintiffs and Defendant were bound by the N.D. Cal. PLR, they would have *no more than 30 days* to exchange preliminary claim constructions once Defendant has produced its ANDA No. 90-040. Defendant is currently scheduled to produce its ANDA no later than June

[4] In fact, under the N.D. Cal. PLR, a plaintiff provides its infringement contentions only 10 days after the initial case management conference, *without any fact discovery whatsoever.*

23, 2008.[5] This provides Plaintiffs with at least 46 days between receipt of Defendant's ANDA and exchange of claim construction charts. In light of the N.D. Cal. PLR and the general judicial trend for early claim construction, a schedule can be set in which the record can be sufficiently developed for claim construction prior to the completion of fact discovery.

Plaintiffs' motivation to delay claim construction is suspect because it increases the likelihood that litigation will continue after the expiration of the 30-month stay thereby potentially allowing Plaintiffs market exclusivity for a longer period of time. Plaintiffs' delay tactics violate their legal obligation in ANDA cases to expedite the litigation. *Imperial Chemicals Indus., PLC v. Barr Labs., Inc.*, 126 F.R.D. 467, 474 (S.D.N.Y. 1989). To this end, if the Court does not adopt Defendant's proposal, Defendant respectfully requests the Court to shorten the length of the 30-month stay by six months. *See Glaxo, Inc. v. Torpharm, Inc.*, 1996 WL 288524 at *2 (N.D. Ill. May 30, 1996), *citing* 21 U.S.C. § 355(j)(4)(B)(iii) (where a party fails to reasonably cooperate in expediting matters, court is empowered to increase or decrease the 30 month stay).

III. CONCLUSION

Defendant respectfully requests the Court to schedule early claim construction proceedings.

Dated: May 30, 2008

Respectfully submitted,

By /s/ MonaGupta
Robert S. Silver
Mona Gupta
William J. Castillo
CAESAR, RIVISE, BERNSTEIN,

[5] As early as January 8, 2008 (*see* Exh. A at 21, which is erroneously dated 2007), Defendant had offered Plaintiffs access to its ANDA No. 90-040 for the purpose of determining infringement. Plaintiffs refused Defendant's offer. Defendant is not responsible for the fact that Plaintiffs do not yet have the ANDA. Plaintiffs should not be heard to complain, therefore, that they have insufficient time to analyze the ANDA to determine which claims are allegedly at issue.

COHEN & POKOTILOW, LTD.
1635 Market Street, 11th Floor
Philadelphia, PA 19103
Telephone: (215) 567-2010
Facsimile: (215) 741-1142
rssilver@crbcp.com

and

Robert B. Breisblatt
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe Street
Chicago, IL 60661
Telephone: (312) 902-5480
Facsimile: (312) 577-8792
Robert.Breisblatt@kattenlaw.com

Attorneys for Defendant, Pentech Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of May, 2008, a true and correct copy of the foregoing **PENTECH'S REPLY BRIEF IN SUPPORT OF HOLDING CLAIM CONSTRUCTION PROCEEDINGS CONCURRENTLY WITH DISCOVERY** is being electronically filed as well as mailed, via United States Postal Services, first class mail, postage prepaid in an envelope addressed to:

Sarah R. Wolff
Jennifer Yule DePriest
REED SMITH LLP
10 South Wacker Drive, 40th Floor
Chicago, IL 60606-7507
swolff@reedsmith.com
jdepriest@reedsmith.com

and

Robert L. Baechtold
Scott K. Reed
Filko Prugo
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3800
rbaechtold@fchs.com
sreed@fchs.com
fprugo@fchs.com

/s/ Mona Gupta
Mona Gupta