

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

	:	
DEPOMED, INC,	:	
	:	
Plaintiff(s),	:	Civil Action No. 12-1358 (JAP)
	:	
v.	:	
	:	OPINION
ACTAVIS ELIZABETH LLC, et al.	:	
	:	
Defendant(s).	:	
	:	

Presently before the Court is a motion by Actavis Elizabeth LLC and Actavis LLC (“Defendants”) to amend their invalidity contentions with respect to U.S. Patent No. 6,635,280 (the “ ‘280 patent”). Specifically, Defendants seek to supplement their Invalidity Contentions with respect to their allegations that the asserted claims in the ‘280 patent are invalid as indefinite. The Court held oral argument on the motion on May 5, 2014.¹ For the reasons below, Defendants’ motion is denied.

I. Background

In their Invalidity Contentions to the ‘280 patent dated August 24, 2012, Defendants state that the asserted claims of the ‘280 patent are invalid as indefinite “because the claim limitation ‘is of a size exceeding the pyloric diameter in the fed mode’ is indefinite.” Murata Decl.² Ex. 4 at 169. The contention continues to generally state that

[t]he term is not one that is readily understood as having a defined meaning by one of ordinary skill in the art. The ‘280 patent also does not sufficiently

¹ A number of other motions were heard on that date and were decided from the bench.
² “Murata Decl.” refers to the Declaration of Jason T. Murata submitted in support of this motion.

explain how one of ordinary skill in the art is to determine whether a particular dosage form satisfies the claim limitation.

Id.

On April 11, 2014, the last day of expert discovery, Defendants deposed Plaintiff's expert, Dr. Gary Annunziata. As characterized by Defendants, Dr. Annunziata testified that he could not identify what specific dimensions would be "a size exceeding the pyloric diameter in the fed mode" as required by the '280 patent claims. *See* Def. Br. 4-5.

On April 14, 2014, during a conference call with the Magistrate Judge, Defendants informed Plaintiff and the Court that it would like to move to supplement their invalidity contentions to include the information obtained from Dr. Annunziata's deposition in support of its contention that the '280 patent is invalid as indefinite. On April 15, 2014, Defendants served their Supplemental Invalidity Contentions on Plaintiff and asked whether Plaintiff intended to object to a motion to amend the contentions. On April 17, 2014, Plaintiff advised that it intended to object. This motion followed. *See* D.I. 288 (filed April 22, 2014).

Trial of this matter is scheduled to begin on May 12, 2012.

II. Analysis

This district's Local Patent Rules permit contentions to be amended "by order of the Court upon a timely application and showing of good cause." Local Patent Rule 3.7. Pursuant to Rule 3.7, a court may permit a party to amend its invalidity contentions provided the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 10-6108,

2012 WL 3133943 at *2 (D.N.J. July 30, 2012). The rule provides a “non-exhaustive” list of examples of circumstances that may support a finding of good cause including:

(a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; (d) disclosure of an infringement contention by a Hatch–Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated; and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines.

Local Patent Rule 3.7. In addition, “courts have also considered other factors in determining whether good cause exists: (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings.” *LMT Mercer Group, Inc. v. Maine Ornamental, LLC*, 2014 WL 284238, *6 (D.N.J., January 24, 2014).

The Local Patent Rules “are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 08–5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). However, while amendments to contentions are not granted as liberally as requests for amendments to pleadings, the Patent Rules retain some degree of flexibility and are not intended to be “a straitjacket into which litigants are locked from the moment their contentions are served.” *Id.*

Applying the above factors, the Court shall deny Defendants’ motion. The Court finds that Defendants unreasonably delayed in asserting the indefiniteness issue in this matter and

that no good cause exists to permit the amendment. Although Defendants included the issue of indefiniteness in the contentions it served nearly two years ago, Defendants did not assert the issue in the litigation until the 11th hour. For example, the indefiniteness defense was not even hinted at during claim construction, despite the fact that the parties presented and the Court construed the term “is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode.” Indeed, as Plaintiff points out, Defendants claim construction expert did not opine that he could not understand the meaning of “is of a size exceeding the pyloric diameter in the fed mode;” rather, Defendants provided an affirmative construction for the disputed term without mention of the possibility that an indefiniteness argument would be raised later.

Nor did Defendants assert the indefiniteness defense in their opening or their rebuttal expert reports during expert discovery, despite being aware that, consistent with Dr. Annunziata’s testimony, the size of the human pylorus is not a fixed number but can vary -- Defendants’ owned expert opined as such (but, notably, that opinion was offered in the context of noninfringement and not indefiniteness). *See* Oral Argument Tr. 23-24 (Defendants’ counsel noting that according to Defendants’ expert Dr. Friend, the pyloric diameter of a human varies by 1.4 centimeters.) Thus, Defendants were aware of the information included in Dr. Annunziata’s testimony prior to Dr. Annunziata’s deposition. There is simply no reason why Defendants could not have asserted the issue earlier.

Given Defendants’ delay in asserting the indefiniteness issue, the Court further finds that Plaintiff would be unduly prejudiced if amendment to the contentions were permitted on the eve of trial. The parties have not engaged in any discovery on the issue, and, given the

timeframe to trial, Plaintiff would have insufficient time to prepare for trial on the issue by the start of trial on May 12th. Consequently, the motion is denied.

III. Conclusion

For the reasons stated above, Defendants' motion to amend their Invalidity Contentions is denied. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: May 8, 2014