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BY ECF & EMAIL

Hon. Paul A. Crotty
United States District Judge
United States Courthouse
500 Pearl Street, Room 735
New York, NY 10007

Re: *Kowa Company, Ltd. et al. v Aurobindo Pharma Limited et al.*, and related cases, 14-cv-2497-PAC, 14-cv-2647-PAC, 14-cv-2758, 14-cv-2759, 14-cv-2760-PAC, and 14-cv-5575-PAC.

Dear Judge Crotty,

Our firm, with Rakoczy Molino Mazzochi Siwik LLP, represents the Mylan Defendants in this matter. We submit the within letter brief on behalf of all Defendants in the related matters. This brief addresses the question of whether the Court should consider indefiniteness during the *Markman* proceedings in this case.¹

Argument: It is appropriate to consider indefiniteness during *Markman*.

“Whether a claim complies with the definiteness requirement of 35 U.S.C. § 112 ¶ 2 is a matter of claim construction, which we review de novo.” *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). Because indefiniteness is a question of law regarding the scope of the claims, it is “in effect part of claim construction.” *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012) (holding indefiniteness defense was not waived when raised during claim construction hearing and again on summary judgment but not at trial); *see also Auxilium Pharm., Inc. v. Watson Labs., Inc.*, No. 12-3084, 2014 WL 2624780, *4 (D.N.J. June

¹ For the convenience of the Court, Defendants sought to include a placeholder in the case schedule submitted today identifying those topics on which the Court had ordered letter briefing. Plaintiffs refused to include this. Thus, the non-inclusion of the issue in the proposed schedule should not be construed as a waiver by Defendants on the issue.

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12, 2014) (The issue “before the Court is not whether ‘indefiniteness is a question of law and in effect part of claim construction.’ The Federal Circuit has clearly answered that question in the affirmative.”) (internal citations omitted).

In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014), the Supreme Court held that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Post-*Nautilus*, the Federal Circuit has evaluated indefiniteness issues decided during claim construction proceedings by the district court. See *Interval Licensing LLC v. AOL, Inc.*, Nos. 2013-1282, 2013-1283, 2013-1284, 2013-1285, 2014 WL 4435871, *2-5 (Fed. Cir. Sept. 10, 2014) (district court’s claim construction order considered whether phrases were “highly subjective” or “lack...objective boundaries” rendering them indefinite). District courts after *Nautilus* have also considered indefiniteness issues during claim construction. In this regard, one recent decision by Chief Judge Simandle in New Jersey, *Mycone Dental Supply Co., Inc. v. Creative Nail Design, Inc.*, No. 11-4380, 2014 WL 3362364 (D.N.J. July 9, 2014), noted that *Nautilus* “changed the standard for indefiniteness such that there is a new standard of proof and a new role for experts at the claim construction phase when, as in this case, there are arguments that claims are indefinite.” *Id.* at *1. The Court explained that “[t]he Court’s present reading of *Nautilus* indicates that experts may have increased significance in claim construction” under the reasonable certainty standard; “*Nautilus* affects an ultimate issue in the case and, because ***indefiniteness is a significant issue to be adjudicated at claim construction***, *Nautilus* impacts the *Markman* proceedings.” *Id.* at *4 (emphasis added).

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Defendants here would like to raise indefiniteness defenses comparable to those decided during claim construction in the cases above (*e.g.*, whether terms are improperly subjective terms of degree, lack objective boundaries or fail to provide clear notice of what is claimed sufficient to satisfy the “reasonable certainty” standard). It is appropriate for the Court to address these issues during the claim construction proceedings because resolution of these issues in Defendants’ favor may be case-dispositive for one or all of the patents asserted in this case.² Even if indefiniteness is decided against Defendants during claim construction, resolution of indefiniteness issues at the claim construction phase will result in more efficient proceedings because the parties’ expert reports can thereafter apply the Court’s claim construction on disputed terms.

Defendants thus respectfully submit that, because they have identified indefiniteness issues, and the same underlying evidence this Court will consider at the *Markman* proceedings will also require consideration for indefiniteness, it is appropriate to address them both in a single combined claim construction proceeding as a matter of law.

* * *

Accordingly, Defendants respectfully request that this Court order the following:

Indefiniteness issues may be raised during *Markman* proceedings. Defendants’ opening brief on indefiniteness shall be submitted May 6, 2015; Plaintiffs’ response on June 8, 2015; and Defendants’ reply on June 15, 2015.

Respectfully submitted,

/s Jakob B. Halpern

Jakob B. Halpern

cc: All counsel of record (by ECF & email)

² Nor do Defendants wish to be in a position where Plaintiffs argue that an indefiniteness issue could have been raised during claim construction proceedings, and is therefore waived if raised in expert reports.