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October 10, 2014

VIA ECF AND U.S. MAIL

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 Ltd., et al., and related cases*
C.A. No. 14-cv-2497, -2758, -2647, -2760, -2759, -5575 (S.D.N.Y.) (PAC)
Letter Brief on Indefiniteness Defense

Dear Judge Crotty:

We represent plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. ("Plaintiffs") in the above-captioned litigation. Pursuant to this Court's Order from the October 6, 2014 Conference, we respectfully submit this letter brief in opposition to Defendants' request that the Court include a disposition of Defendants' yet-unspecified indefiniteness defense(s) as part of any Markman proceeding. Defendants are essentially trying to create an opportunity to seek a premature final determination of an indefiniteness defense(s) before the factual and expert evidence on the issues are obtained.

"[T]he weight of the jurisprudence disfavors indefiniteness determinations at the *Markman* stage of patent litigation." *CSB–System Intern. Inc. v. SAP America, Inc.*, No. 10–2156, 2011 WL 3240838, at *19 n. 16 (E.D. Pa. Jul. 28, 2011)). This District has "refrain[ed] from ruling on this issue of indefiniteness prior to trial." *In re OxyContin Antitrust Litig.*, 04 MD. 1603 SHS, 2014 WL 2198590, at *4 (S.D.N.Y. May 27, 2014) (citing *In re OxyContin Antitrust Litig.*, 965 F. Supp. 2d 420, 432 n.3 (S.D.N.Y. 2013); *Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09-cv-0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011). Similarly, in

Alcon Research, Ltd., an ANDA case relied on by this District in the *In re OxyContin Antitrust Litig*, *supra*, the District of Delaware concluded that "the indefiniteness issue is best decided at trial and [we] defer consideration on it until that time." 2011 WL 3901878, at *16 (collecting cases). "[S]everal well-settled principles tend to discourage such rulings at the *Markman* stage." *CSB–System Intern. Inc.*, 2011 WL 3240838, at *17. First, "there is a high burden of proof on a party challenging [a] patent based on indefiniteness, which is difficult to meet at the early stages of litigation." *Id.* Second, "unlike a *Markman* proceeding that gives meaning to patent claims, indefiniteness invalidates claims entirely." *Id.* at *18; *accord*, *Koninklijke Philips Electronics N.V. v. Zoll Med. Corp.*, 914 F. Supp. 2d 89, 101 (D. Mass. 2012).

Moreover, issues of indefiniteness are often the subject of a "'largely factual' inquiry"; thus, the ensuing "'battle of the experts' is not, therefore, properly resolved at the claim construction phase. *Koninklijke Philips Elect. N.V.*, 914 F. Supp. 2d at 101 (quoting *Takeda Pharm. Co. v. Handa Pharms.*, LLC, 2012 WL 1243109, at *16 (N.D. Cal. Apr. 11, 2012). While "[i]t may be true that determining the indefiniteness of claim language is a question of law 'that is drawn from the court's performance of its duty as the construer of patent claims,' which is the same duty that gives rise to the *Markman* hearing . . . this does not outweigh the … practical considerations that militate against determining indefiniteness prior to the end of fact or expert discovery." *CSB–System Intern. Inc.*, 2011 WL 3240838, at *17-19 (quoting *Exxon Research & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1375 (Fed. Cir. 2001); *Waddington N. Am., Inc. v. Sabert Corp.*, No. CIV.A.09–4883, 2010 WL 4363137, at *3 (D.N.J. Oct. 27, 2010)); *see also Computer Stores Nw., Inc. v. Dunwell Tech, Inc.*, CV-10-284-HZ, 2011 WL 2160931, at *38 (D. Or. May 31, 2011) ("[A]ny argument regarding invalidity of the claim for . . . indefiniteness of

the claim is 'neither appropriate nor acceptable at the claim construction stage.")

Finally, while the U.S. Supreme Court recently clarified the standard for indefiniteness under 35 U.S.C. § 112, ¶ 2 in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (2014), nothing in that opinion negates the weight of authority finding that indefiniteness should be addressed after *Markman*.[1] If anything, the clarified standard of the *Nautilus* case heightens the importance of obtaining the factual and expert evidence on the issue before ruling on indefiniteness. As with any invalidity defense, the presumption is that the claims are valid, and invalidity must be proven by clear and convincing evidence.

This Court should, therefore, deny defendants' request to deviate from the "weight of the jurisprudence disfavor[ing] indefiniteness determinations at the *Markman* stage of patent litigation," *CSB–System Intern. Inc.*, 2011 WL 3240838, at *19 n.16. Consistent with practice in this District, the Court should "refrain[] from ruling on this issue of indefiniteness prior to trial." *In re OxyContin Antitrust Litig.*, 2014 WL 2198590, at *4.

Thank you for your consideration.

Respectfully submitted,

David G. Conlin

cc: Counsel of record (via ECF)

[1] Contrary to defense counsel's representation at the October 6, 2014 Conference, the Supreme Court's decision in *Nautilus* did not isolate the analysis of indefiniteness from the subsidiary fact findings historically underpinning that determination. 134 S. Ct. 2129, n.10. To the contrary, the Court noted that no party raised "any contested factual matter," and specifically declined to address the evidentiary burden pertaining to such fact issues, noting, "[w]e leave these questions for another day." *Id.*