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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

*The applicants are DENIED
obligated to address secondary
round of expert reports.*
*The defendants are
consideration in their first
round.*
No relevant
Paul Halpern
USNS

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 burden is on Plaintiffs to come forward first with expert opinions on secondary considerations in their expert reports, with Defendants responding in a subsequent round.¹

Argument: Plaintiffs have the initial burden of production to identify any allegedly relevant secondary considerations they intend to present at trial.

Under the Supreme Court’s decision in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), an analysis of obviousness requires the Court to consider any allegedly relevant “secondary” considerations (sometimes called “objective evidence”) suggesting that a challenged invention is non-obvious. Such secondary considerations may include, but are not limited to, commercial success, long-felt but unsolved need, failure of others and copying. *KSR Int’l Co. v.*

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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Teleflex Inc., 550 U.S. 398, 406, 415 (2007); *see also Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000).

Although the accused infringer bears the ultimate burden of proof as to obviousness, the patentee bears the burden of production with regard to secondary consideration evidence. *See Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010) (requiring that the patentee “shows both that there is commercial success” and nexus before “the burden of coming forward with evidence in rebuttal shifts to the challenger”); *Ecolochem*, 227 F.3d at 1376 (producing evidence of secondary considerations was plaintiff’s burden); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392-93 (Fed. Cir. 1988) (patentee has burden of coming forward with evidence of secondary considerations and their nexus to the patented invention); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075, 1078-79, n. 5 (Fed. Cir. 2012). This rule makes common sense, as defendants typically have no way of anticipating which, if any, of the several categories of secondary evidence the patentee will seek to rely on at trial.

Accordingly, Defendants respectfully submit that Plaintiffs should be required to disclose their opinions and evidence of secondary considerations before Defendants are obligated to provide any rebuttal evidence. In particular, Defendants request that Plaintiffs be required to identify any allegedly relevant secondary considerations and related opinions in their opening expert reports due on December 15, 2015.² This will afford Defendants an opportunity to rebut Plaintiffs’ evidence of secondary considerations of non-obviousness rather than guess as to what Plaintiffs’ may be. To do otherwise would be prejudicial and unjust to Defendants.

² At the very least, such disclosure certainly should not be delayed past the second round of expert reports, due on January 29, 2016, so that Defendants have the opportunity to respond in the final round of expert reports.

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* * *

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

Defendants are not obligated to address secondary considerations in their opening round of expert reports. Plaintiffs shall provide their expert opinions on secondary considerations no later than December 15, 2015.

Respectfully submitted,

/s Jakob B. Halpern

Jakob B. Halpern

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