IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd. et al., Plaintiffs, v. Amneal Pharmaceuticals LLC, Defendant.	Civil Action No. 14-CV-2758 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Orient Pharma Co., Ltd., Defendant.	Civil Action No. 14-CV-2759 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Zydus Pharmaceuticals (USA) Inc. et al., Defendants.	Civil Action No. 14-CV-2760 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Apotex, Inc. et al., Defendants.	Civil Action No. 14-cv-7934 (PAC)

Kowa Company, Ltd. et al., Plaintiffs, v. Lupin Ltd. et al., Defendants.	Civil Action No. 15-cv-3935 (PAC)

DEFENDANTS' PROPOSED FINDINGS AND CONCLUSIONS RE:

SECONDARY CONSIDERATIONS OF OBVIOUSNESS REGARDING THE '336 AND '993 PATENTS

PRESENTED ON BEHALF OF ALL DEFENDANTS

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A. Non-obviousness is Not Supported by Any Secondary Indicia of Non-obviousness

1. Secondary indicia of non-obviousness are case law derived circumstantial evidence that shed light on the obviousness determination by drawing inferences from underlying facts. They are found to be probative of whether an invention was obvious or not in that they "inoculate the obviousness inquiry against hindsight." *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377-79 (Fed. Cir. 2012).

2. In *Graham v. John Deere Co. of Kansas,* 383 U.S. 1, 17-18 (1966), the U.S. Supreme Court stated that secondary considerations can include commercial success, long-felt but unsolved need, and the failure of others. Other factors recognized by the Federal Circuit after *Graham* include whether the invention received industry acclamation, the prior art teaches away from the invention, or others have copied the invention. *See, e.g., Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1381 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 974 (2001). Simultaneous invention can argue against any secondary indicia of obviousness. *Ecolochem* at 1379; *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984).

3. While the overall burden in respect of obviousness remains on the challenger, in respect of secondary considerations, the patentee must establish the existence of a secondary consideration supporting non-obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1081 n.8 (Fed. Cir. 2012) (burden of establishing nonobviousness does not shift to patentee, but patentee could not rely on unexpected results because it “failed to offer adequate proof”); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1363 (Fed. Cir. 2012) (“to show that the cooling effects of the combination of WS-23 and menthol was unexpected, [the patentee] needed to demonstrate that the results were

unexpected to a significant degree beyond what was already known about the effect of combining WS-3 and menthol").

4. The burden is also on the patentee to demonstrate a nexus between the secondary indicia of non-obviousness relied upon and the particular claimed invention. *See, e.g., Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (although embodiments of the invention may have enjoyed commercial success, patentee failed to link the commercial success to the patented features).

5. Secondary considerations of non-obviousness cannot overcome a strong showing of obviousness. *Tokai Corp. v. Easton Enterprises*, 632 F.3d 1358, 1371(Fed. Cir. 2011). Here, none of the secondary considerations identified by Plaintiffs overcome the strong case obviousness set forth by Defendants.

B. Plaintiffs Have Failed to Demonstrate the Commercial Success of Livalo® and to Make a Nexus Between the Purported Commercial Success and the Calcium Salt Form of Pitavastatin Which Comprises Livalo®[1]

6. Commercial success is a secondary indicia of non-obviousness. The patentee carries the burden of demonstrating that what is "commercially successful is the invention disclosed and claimed in the patent." *Demarco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

7. To prove commercial success, the patent most establish both: (1) that the product embodying the patented invention is commercially successful (*Cf. Applied Materials Inc. v. Advanced Semiconductor Materials America Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1966) – "[A]patentee need not show that all possible embodiments within the claims were successfully commercialized in order to rely on the success in the marketplace of the embodiment that was

[1] The entire discussion of the lack of Livalo®'s commercial success will be supported by the anticipated testimony of Drs. Hay and Bell.

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