

David G. Conlin

Partner

+1 617 517 5515

fax +1 888 325 9129

dconlin@edwardswildman.com

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 Expert Reports

Dear Judge Crotty:

We represent plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. (“Plaintiffs”) in the above-referenced matter. This letter sets forth Plaintiffs’ position regarding timing of expert reports addressing secondary considerations or any obviousness opinions by Defendants’ experts.

The Defendants in this case bear the burden of proof should they assert that any of the asserted patents are invalid as obvious. *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2245 (2011) (“The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”). This burden is set high – requiring proof by clear and convincing evidence – and never shifts to the plaintiffs. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013) (“[A]s we have often held (most recently in *Cyclobenzaprine*) ..., this burden never shifts during the course of the litigation.”); *see also Symbol Techs. Inc. v. Opticon Inc.*, No. 86 CV 8736 KMW, 1990 WL 58887, at *6 (S.D.N.Y. May 3, 1990) (“The burden of proof is on the defendant to show invalidity by clear and convincing proof and that burden never shifts during the course of the litigation. “), *aff’d* 935

F.2d 1569 (Fed. Cir. 1991). The Defendants' burden on this issue applies to each fact upon which their obviousness positions are based. *Symbol Techs*, 1990 WL 58887 at *6 (citing *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986)).

By contrast, the Plaintiffs bear no burden on the ultimate issue of obviousness. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986) (“[A] patentee need submit no evidence in support of a conclusion of validity by a court or a jury.”). While secondary considerations have been characterized as rebuttal evidence, they must be considered *before* any conclusions are drawn regarding obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (finding that the district court erred by reaching a “conclusion” regarding obviousness before explicitly considering—and rejecting—the objective indicia evidence proffered by the patentee), *reh’g en banc denied* (Jul. 25, 2012), *cert. denied*, 133 S. Ct. 933 (2013); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) (holding that “evidence rising out of the so-called ‘secondary considerations’ must always when present be considered en route to a determination of obviousness.”). To have formed a belief that a patent at issue is obvious, Defendants must have accounted for secondary considerations. *Sensonic, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1071 (Fed. Cir. 1996) (finding opinion of counsel to be flawed noting, “the opinion of counsel makes no mention of Aerosonic's copying and other objective indicia of unobviousness, although precedent requires that these factors be considered.”) (citing *Stratoflex*).

Consistent with these cases and with defendants' ultimate burden, courts have required that the party alleging invalidity address secondary considerations in its opening report. *See e.g., Sanofi-Aventis v. Barr Labs., Inc.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (“[A]lthough

secondary considerations may be characterized as rebuttal evidence, as a practical matter, there is no compelling reason why Defendants should not address same in their opening report.”); *In re Certain MEMS Devices and Products Containing the Same*, Inv. No. 337-TA-700, 2010 ITC Lexis 1123, at *7 (Jun. 29, 2010) (“[R]espondents’ initial expert reports addressing invalidity should have, and clearly could have, included a section addressing secondary considerations”). In this District, Judge Cote recently reached the same conclusion (in responding to the position advanced by Mylan’s counsel in a different Hatch-Waxman case). *See* Ex. A (Mar. 25, 2013 Order in Case No. 12-cv-0024 (DLC) (interpreting the Federal Rules to require that initial expert reports be “complete” and refusing to allow defendants to file a supplemental expert report addressing secondary considerations after plaintiffs’ expert report).

Defendants’ attempt to put their heads in the sand and ignore these key obviousness considerations in their expert reports addressing obviousness is a transparent attempt to facilitate reaching an obviousness conclusion without considering all of the relevant evidence. Defendants should not be permitted to ignore the unexpected results achieved by Livalo[®], the extensive commercial success of Livalo[®], the number of pharmaceutical companies who are so anxious to copy Livalo[®] that they are willing to conduct extensive litigation in this Court, and all the other secondary indicia of non-obviousness. Simply put, there is no reason for Defendants not to address secondary considerations in their opening expert reports.

Thank you for your consideration.

Respectfully submitted,



David G. Conlin

cc: Counsel of Record (Via ECF)