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April 8, 2009

Via ECF

The Hon. Garrett E. Brown, Jr., C.U.S.D.J.
Clarkson S. Fisher Federal Bldg. & U.S. Courthouse
402 E. State Street
Trenton, NJ 08608

Re: *Ortho-McNeil Pharmaceutical, Inc., et al. v. Lupin Pharmaceuticals, Inc., et al.*
Civil Action No. 06-4999 (GEB)(TJB)

Dear Judge Brown:

Enclosed please find a recent opinion from the District Court for the Eastern District of Virginia that Plaintiffs believe is relevant to the pending cross-motions for summary judgment.

In *Photocure ASA v. Dudas*, Civ. Action No. 1:08-cv-718 (E.D. Va. Mar. 31, 2009), Judge O'Grady overturned the Patent Office's determination denying a patent term extension for METVIXIA. In support of its motion for summary judgment, Lupin relied on the Patent Office's determination (Docket No. 59 at 20-23) that METVIXIA was not entitled to a patent term extension because it did not contain a new "active moiety." Additionally, Judge O'Grady concluded that he was bound by the Federal Circuit's decision in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), not the later decision in *Pfizer, Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004). See *Photocure* at 13-14.¹ Judge O'Grady's decision is consistent with the position set forth in Plaintiffs' summary judgment briefs. See, e.g., Plaintiffs' Mem. in Opp. to Defendants' Mot. for Summary Judgment and in Support of Plaintiffs' Cross-Motion for Summary Judgment (Docket No. 61) at 15, n.6.

Respectfully yours,

s/Thomas E. Hastings
Thomas E. Hastings

TEH/cd
Enclosure

¹ In *Glaxo*, the Federal Court rejected the argument that Lupin appears to be advancing in this case that Congress intended the term "active ingredient" in Section 156 to be equivalent to "new chemical entity" or "active moiety." See *Glaxo*, 894 F.2d at 399.



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