

VIA ELECTRONIC FILING

The Honorable Leonard P. Stark
United States District Court, District of Delaware
J. Caleb Boggs Federal Building
844 North King Street, Room 6100
Wilmington, DE 19801-3556

Re: *Warner Chilcott, LLC and Hoffmann-La Roche Inc. v. Apotex, Inc., et. al.*
C.A. Nos. 08-0627, 09-143, and 10-1111 and related cases

Dear Judge Stark:

Last week on Monday, May 7, 2012, Judge Stanley R. Chesler entered summary judgment in the District of New Jersey that the monthly dosing claims for ibandronate in U.S. Patent No. 7,718,634 (which is one of the two patents at issue in this litigation) are invalid as obvious. A copy of that opinion is attached. *See* Attachment A, *Opinion*, D.I. 489 in 2:07-cv-04417-SRC-MAS (D.N.J., May 7, 2012). Defendants Apotex Inc. and Apotex Corp., Mylan Pharmaceuticals Inc., and Sun Pharma Global FZE believe that Judge Chesler's reasoning and analysis in that opinion are equally applicable to the risedronate claims at issue in this litigation over the relevant prior art. In light of that new development, which arose only *after* the deadline for filing summary judgment motions herein, these defendants request leave to file a summary judgment motion now explaining how Judge Chesler's reasoning applies to the analogous claims and prior art in this case and showing that there is no genuine issue of material fact and those claims are invalid for obviousness as a matter of law. If the Court agrees with Judge Chesler's analysis and that it applies analogously to the claims and art in this case, the requested motion will be case dispositive.

Plaintiffs are willing to have defendants present this potentially case dispositive issue to the Court on summary judgment. However, under the circumstances, plaintiffs believe that that the pretrial process and trial should be stayed pending resolution of defendants' motion. In addition, for analogous reasons to those cited by defendants with respect to the issue of obviousness, plaintiffs may want to move for summary judgment on the issue of infringement, to be briefed concurrently with defendants' summary judgment motion on obviousness. Judge Chesler had previously granted partial summary judgment of infringement of U.S. Patent No. 7,410,957 (which is the parent from which the two patents at issue here are continuations). A copy of that opinion is also attached. *See*, Attachment B, *Amended Opinion*, D.I. 259 in 2:07-cv-04417-SRC-MAS (D.N.J., Sep. 2, 2010). The above defendants would not oppose plaintiffs' request to brief the issue of infringement at the same time that defendants brief the issue of obviousness, and would agree with plaintiffs' request to stay the trial and pretrial process pending resolution of these motions.

This case is currently set for trial beginning July 23. The final pretrial conference is scheduled for July 2, and the Final Pretrial Order is due on June 18. Another patent, U.S. Patent 5,583,122, and an associated six-month period of pediatric exclusivity currently prevent any of the defendants from receiving FDA approval to market the generic products at issue in this case

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until June 10, 2014. Apotex Inc. and Apotex Corp., Mylan Pharmaceuticals Inc., and Sun Pharma Global FZE did not challenge the '122 patent. Teva Pharmaceuticals USA Inc. previously challenged that other patent, but did not prevail.

Defendant Teva Pharmaceuticals USA Inc. does not join in this request for leave to file summary judgment motions. Teva Pharmaceuticals USA, Inc. believes that the case should proceed to trial, and submission of dispositive motions to the court would present a significant risk that the issues would not be fully resolved before June 10, 2014.

The parties jointly request a telephonic status conference with the Court at the Court's earliest convenience and availability to discuss this scheduling matter and how best to proceed with resolving this case.

Respectfully,

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