

Frederick L. Cottrell, III
Director
302-651-7509
Cottrell@rlf.com

January 4, 2013

VIA CM/ECF FILING

The Honorable Leonard P. Stark
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Unit 26, Room 6124
Wilmington, DE 19801-3555

Re: *Warner Chilcott Company, LLC et al. v. Teva Pharmaceuticals USA, Inc.*,
D. Del. No. 08-CV-627 and Consolidated Actions

Dear Judge Stark:

I write on behalf of Plaintiffs Warner Chilcott Company, LLC and Hoffman-La Roche, Inc. ("Plaintiffs") in the above-captioned, related Hatch-Waxman cases involving Once-A-Month Actonel®.

On December 28, 2012, Defendant Mylan Pharmaceuticals ("Mylan") submitted a letter bringing the Court's attention to the Federal Circuit's recent decision in *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344 (Fed. Cir. 2012). The assertions in Mylan's letter are incorrect, because the *Santarus* decision is inapplicable.

None of the claims at issue in this above-referenced case contain a negative limitation as described in the *Santarus* case. In *Santarus*, the sole independent claim at issue contained the language, "wherein the composition contains no sucralfate." 694 F.3d at 1350. No such limitation exists with respect to a "loading dose" in the asserted claims of the patents-in-suit.

Nor does the prosecution history add negative limitations to the asserted claims. For example, the patentee here amended Claim 10 of the '634 patent to clarify that the claimed method must consist essentially of administering the 150mg dosage. Claim 10 of the '634 patent reads, "A method for treating or inhibiting postmenopausal osteoporosis . . . consisting essentially of orally administering . . . once monthly on a single day . . . an amount of the pharmaceutically acceptable salt of risedronic acid that is equivalent to about 150 mg of risedronic acid." As such, the language of Claim 10 necessarily excludes the use of a method requiring a loading dose, but *Santarus* does not require that a patent provide a rationale for



The Honorable Leonard P. Stark

January 4, 2013

Page 2

excluding every method not covered by the claims to satisfy the written description requirement. Accordingly, the holding and rationale of the Federal Circuit in *Santarus* is inapposite.

Respectfully submitted,

/s/ Frederick L. Cottrell, III

Frederick L. Cottrell III (#2555)
cottrell@rlf.com

FLC,III/kdm

cc: All Counsel of Record (via electronic mail)