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VIA CM/ECF FILING AND HAND DELIVERY

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

Re: *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 08-627-LPS; *Procter & Gamble Co. v. Sun Pharma Global, Inc.*, C.A. No. 09-061-GMS; *Procter & Gamble Co. v. Apotex, Inc.*, C.A. No. 09-143-LPS; *Warner Chilcott Company, LLC v. Mylan Pharmaceuticals Inc.*, C.A. No. 10-285-LPS; *Warner Chilcott Company, LLC v. Sun Pharma Global, Inc.*, C.A. No. 10-1085-UNA

Dear Judge Stark:

I write on behalf of all parties in the above-captioned, related Hatch-Waxman cases involving Once-A-Month Actonel®. As Your Honor is aware, four of these cases were recently consolidated at the request of the parties for all pre-trial purposes and put on a unified case schedule per order of the Court dated November 1, 2010 (C.A. No. 08- 627-LPS, D.I. 105). The already consolidated actions are:

- *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, No. 08-627-LPS (“the Teva Action”);
- *Procter & Gamble Co. v. Sun Pharma Global, Inc.*, No. 09-061-GMS (“the Sun ‘938 Action”);
- *Procter & Gamble Co. v. Apotex, Inc.*, No. 09-143-LPS (“the Apotex Action”);
- and
- *Warner Chilcott Company, LLC v. Mylan Pharmaceuticals Inc.*, No. 10-285-LPS (“the Mylan Action”).

In the last several weeks, however, the Plaintiffs have received additional Paragraph IV certification notices from the Defendants in three of these four cases in regard to an additional patent – U.S. Patent No. 7,718,634 (“the ‘634 patent”) – which was more recently listed in the Orange Book for the Once-A-Month Actonel® product to which the Defendants’ generic drug



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applications pertain. The '634 patent is in the same patent family as U.S. Patent No. 7,192,938 ("the '938 patent"), which is asserted in the first four consolidated actions.

This past Friday, Plaintiffs filed a new infringement suit against Sun Pharma Global, Inc. ("Sun") under the '634 patent (C.A. No. 10-1085-UNA ("the Sun '634 Action")). Additional suits against two of the other Defendants under the '634 patent will follow within the next two months, and Plaintiffs understand that a Paragraph IV certification notice relating to the '634 patent from the remaining Defendant is forthcoming. The parties have discussed this inevitable course of events and agree that, in an effort to conserve both the parties' and the Court's resources and to promote efficiency, it makes sense to consolidate actions under the '634 patent with the existing consolidated litigation. The parties also agree that it would not be most sensible or efficient to proceed under the current schedule and undertake tasks such as claim construction, fact depositions, and expert discovery before such time as additional issues that are raised by the '634 patent can simultaneously be addressed.

Of most immediate impact would be the claim construction process that is currently in the briefing stage. The parties conferred about the issues in dispute concerning the '938 patent and submitted opening briefs concerning the claim terms in dispute on November 22, 2010.¹ Given that additional terms of the related '634 patent will almost certainly need to be construed, the parties believe that further briefing and the *Markman* hearing should be delayed to integrate additional claim construction disputes arising from the terms of the '634 patent. The parties believe that a delay of claim construction events by approximately five months would allow enough time for the new suits under the '634 patent to be initiated and consolidated into the existing consolidated case, such that all claim construction issues on the '938 patent and the '634 patent may be addressed together. The parties also believe that such a delay would allow for the parties to "catch up" with discovery relating to the '634 patent, such that single depositions of fact witnesses covering issues arising from both related patents may be undertaken before unified expert discovery begins.

Accordingly, the parties respectfully submit the attached Proposed Amended Scheduling Order for the Court's consideration and request that the Court vacate the existing Amended Consolidated Scheduling Order, dated November 1, 2010 (C.A. No. 08-627-LPS, D.I. 105). The attached proposed schedule anticipates a consolidation of the new cases being initiated under the '634 patent and reflects an initial delay of current schedule by approximately five months, which the parties believe will allow enough time for the new suits under the '634 patent to be

¹ Plaintiff Warner Chilcott and Defendant Teva Pharmaceuticals USA, Inc. ("Teva") also submitted briefing in regard to construction of certain terms of U.S. Patent No. 6,165,513 ("the '513 patent"), which is at issue in the Teva Action and in a declaratory judgment claim in the Apotex Action.

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consolidated and for the parties to prepare to address the '634 patent as part of the claim construction proceedings and discovery already underway with regard to the '938 patent.²

Should Your Honor wish, the parties would, of course, be happy to avail themselves for a teleconference to discuss these matters at the Court's convenience.

Respectfully,



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LDH/kdm
cc: All Counsel of Record (via email)

² The Proposed Amended Scheduling Order increases the number of interrogatories and requests for admission allowed from each side to 40 to accommodate additional written discovery for the '634 patent, and the parameters provided for claim construction briefing contemplate that the parties will submit replacement versions of the Joint Claim Construction Statement and their opening briefs on the '938 patent to sweep in new issues arising from the '634 patent. (Opening briefs from Warner Chilcott/P&G and Teva on terms from U.S. Patent No. 6,165,513 will remain unchanged.)