



September 23, 2016

VIA ECF

Hon. William J. Martini, U.S.D.J.
U.S. District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

**RE: *Daiichi Sankyo Company, Limited et al. v. Mylan Pharmaceuticals, Inc., et al.*,
Civil Action Nos. 06-3462, 07-3039, and 08-2752 (WJM)(MF) (Consolidated)**

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Dear Judge Martini:

We, together with Fitzpatrick, Cella, Harper & Scinto, represent Daiichi Sankyo Company Limited and Daiichi Sankyo, Inc. (collectively, "Daiichi Sankyo" or "Plaintiffs") in the above Hatch Waxman actions. We respectfully request an expedited briefing schedule for a motion we filed today. The background is as follows.

In 2009 Your Honor entered a Judgment that provided in relevant part that Defendants ("Mylan") are "enjoined, until the expiration date of [Daiichi Sankyo's] '599 patent, including all extensions thereof, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the [generic olmesartan medoxomil] products which are subject of [Mylan's] ANDA Nos. 78-276, 78-827, and 90-398." D.I. 143, at 2-3. Subsequently Daiichi Sankyo was granted from the FDA a six month extension of pediatric exclusivity. Now, as the extended date approaches, a dispute has arisen over the precise date the Judgment restraints on Mylan end. Plaintiffs therefore filed a motion today seeking clarification of the Judgment [D.I. 154]. Because the date in question is barely a month away we are seeking an expedited briefing schedule.

As explained in our motion papers, the parties dispute when Mylan is free of the restraints in the Judgment and allowed to launch its generic olmesartan medoxomil products. Mylan believes that it is free to launch on October 25, 2016, whereas Daiichi Sankyo contends that the Judgment enjoins Mylan until October 26, 2016.¹ A one day

¹ This dispute arose as Mylan's anticipated launch date approached and Daiichi Sankyo noticed that the Judgment did not speak to the controlling date, as extended. We therefore asked Mylan to stipulate that the precise date is October 26. Mylan refused, necessitating this motion to clarify. It is filed in accordance with Fed. R. Civ. P. 60(a), which permits correction of, *inter alia*, a "mistake arising from oversight or omission **whenever one is found in a judgment.**" (emphasis added); *see, e.g., Takeda Pharm. Co.*

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difference represents significant revenue to Daiichi Sankyo, as detailed in the motion papers. If the dispute is not resolved before October 25 and Mylan launches, a potentially complex damages hearing would be necessary. As October 25 is so near, Plaintiffs respectfully propose a schedule that will have briefing completed well in advance of the disputed dates in order to allow as much time as possible for Your Honor to consider the parties' arguments and resolve the issue.²

If the briefing schedule proposed below meets with Your Honor's approval, we respectfully request the Court to So Order this letter and have it entered on the docket. Plaintiffs are available at the Court's convenience if Your Honor has any questions. Thank you for your consideration.

ACTION	DEADLINE
Plaintiffs' Opening Brief	Filed on September 23, 2016
Defendants' Opposition Brief	October 7, 2016
Plaintiffs' Reply Brief	October 14, 2016

Respectfully,

s/William J. O'Shaughnessy

William J. O'Shaughnessy

cc: Counsel of Record (via email)

v. Teva Pharms. USA, Inc., No. 06-33-SLR, 2009 WL 3738738, at *3 (D. Del. Nov. 9, 2009) (granting motion to clarify judgment to prevent defendant from launching its generic product the following day after conducting an emergency hearing and concluding that the injunction should remain in effect for one additional day).

² Plaintiffs reached out to Defendants' counsel to try to reach an agreement on the briefing schedule proposed herein, but Defendants' counsel did not respond.