

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

ASTRAZENECA AB,  
Patent Owner.

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IPR2015-01340  
Patent RE44,186

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**JOINT STIPULATION REGARDING JOINDER**

## I. INTRODUCTION

After a telephone hearing on June 17, 2016, the Board authorized the parties in IPR2015-01340, IPR2016-01029 and IPR2016-01104 to file a joint stipulation “explaining the agreement between Petitioners Mylan, Wockhardt, Amneal and Sun with respect to the level of cooperation that will be maintained if the motions for joinder are granted IPR2016-01029, and IPR2016-01104.” Paper 22.

AstraZeneca is the patent owner; Mylan, the original petitioner; Wockhardt, Amneal and Sun, the joining petitioners.

AstraZeneca has advised the petitioners that it continues to oppose joinder of these additional parties as time-barred and for reasons addressed in its Oppositions. IPR2016-01029, Paper 8 (May 31, 2016); IPR2016-01140, Paper 12 (June 15, 2016). The Board requested that the Parties propose a joint stipulation to ensure, that if Joinder is granted, that Amneal, Sun, Wockhardt, and Mylan cooperate to provide a single voice in the joined proceeding, whether at hearings, at depositions, in filings, or otherwise.

## II. THE AGREEMENT

Amneal, Sun, and Wockhardt have agreed with Mylan, the “Lead Petitioner”, to share the use and, after joinder, the *pro rata* costs of Mylan’s experts in this IPR proceeding in exchange for continuing access to the experts in

the event that Mylan no longer participates in the review. As long as Mylan is a party to the review, Amneal, Sun, and Wockhardt will:

- coordinate any communications with Mylan's experts through Mylan;
- not produce their own testifying witness ; and
- not file substantive papers (except for those associated with Board-approved motions that do not affect Mylan or Mylan's position).

Mylan, Amneal, Sun and Wockhardt will confer and cooperate on the consolidated filings but, as long as Mylan is a party to the review, Mylan will make all final decisions, will retain responsibility for oral argument (including telephone hearings and appeals) and Amneal, Sun, and Wockhardt will not receive separate time and will not separately argue during oral argument, including telephone hearings and appeals, except when addressing Board-approved motions that do not affect Mylan or Mylan's position.

Mylan, Amneal, Sun and Wockhardt have agreed to coordinate the discovery and testimony relating to witnesses but, as long as Mylan is a party to the review, Mylan will make all final decisions. In particular, as long as Mylan is a party to the review, Amneal, Sun, and Wockhardt will not separately file or serve objections or discovery requests, will not receive separate cross examination or redirect time, will not separately cross examine or redirect any witness, and they

stipulate that cross examinations will occur within the timeframe normally allotted to one party without a need for extension in light of the joinder.

Whether Mylan remains a party or not, Amneal, Sun and Wockhardt will not actively seek to change the opinion of Mylan's current expert (Dr. Rotella) or present attorney arguments that are inconsistent with Dr. Rotella's opinions or the positions taken by Mylan in the copending litigation.

If either of the joining parties no longer participates in the reviews the remaining parties will maintain this agreement. If Mylan is no longer a party to the review, the remaining joined parties shall meet and confer to select a new Lead Petitioner. Any such new Lead Petitioner will effectively take Mylan's place in this stipulation and all remaining petitioners will continue to be bound hereby.

Nothing in this Joint Stipulation Regarding Joinder is intended to limit the evidence the Board may consider pursuant to *Genzyme Therapeutic Partners Products LP v. Biomarin Pharma, Ltd*, \_\_\_ F.3d \_\_\_ (Fed. Cir. June 14, 2016).

### **III. PATENT OWNER'S VIEW ON THE LEVEL OF COOPERATION**

AstraZeneca has advised the petitioners that it maintains that joinder is not proper for the reasons provided in its respective oppositions to the motions for joinder. If joinder is granted, AstraZeneca advises that it does not request any additional level of cooperation other than that specified in the previous section.

Respectfully submitted,

Dated: July 1, 2016

/ Steven W. Parmelee /

Steven W. Parmelee

Lead counsel for Mylan Pharmaceuticals, Inc.

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