

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2016-01029
Patent RE44,186

PATENT OWNER'S PRELIMINARY RESPONSE

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I. Introduction

Wockhardt's Petition for *inter partes* review ("IPR") is time-barred under 35 U.S.C. § 315(b), having been filed more than one year after Wockhardt was served with a Complaint alleging infringement of AstraZeneca's RE44,186 patent ("the RE'186 patent"). To avoid the § 315(b) bar, Wockhardt proposes joinder to instituted IPR2015-01340 (*Mylan Pharms. Inc. v. AstraZeneca AB*) (the "Mylan IPR"). Joinder is not warranted here, because Wockhardt's Petition was not timely filed and its participation in the Mylan IPR is unnecessary and will only complicate that proceeding.

II. Procedural History Relevant to 35 U.S.C. § 315(b)

On May 28, 2014, AstraZeneca served Wockhardt with a Complaint for infringement of the RE'186 patent based on Wockhardt's submission of an Abbreviated New Drug Application ("ANDA") to market generic versions of AstraZeneca's pharmaceutical product ONGLYZA[®]. **Ex. 2001** at 4, D.I. 1 (Complaint entered May 23, 2014), D.I. 7 (Wockhardt served on May 28, 2014). Almost two years after being served with a Complaint in the district court action, Wockhardt filed a Petition for IPR of the RE'186 patent and a motion to join the Mylan IPR. IPR2016-01029, Paper 1 at 1, n.1 (filed May 11, 2016), Paper 3.

The RE'186 patent at issue in Wockhardt's Petition, is the same patent at issue in the Mylan IPR and the district court action. *Mylan Pharms.*, IPR2015-

01340, Paper 3 (June 4, 2015). The district court case has been consolidated with five total defendants, including both Wockhardt and Mylan. **Ex. 2002** at 15 (Remark entered Oct. 8, 2014). Trial is set for September 19, 2016, in Delaware District Court. **Ex. 2002** at 15 (Order entered Oct. 20, 2014).

After Wockhardt filed its Petition, other defendants to the district court action similarly filed time-barred petitions for IPR and similarly requested joinder to the Mylan IPR. *See Sun Pharm. Indus., Ltd., v AstraZeneca AB*, IPR2016-01104, Papers 3-4; *Aurobindo Pharma U.S.A., Inc. v AstraZeneca AB*, IPR2016-01117, Papers 1, 3. While the Petitioners in IPR2016-01340 (Mylan), IPR2016-01029 (Wockhardt), and IPR2016-001104 (Sun), entered into a joint stipulation regarding the level of cooperation among Petitioners in the event joinder is granted, the Petitioner in IPR2016-01117 (Aurobindo) has not. IPR2015-01340, Paper 23; IPR2016-01029, Paper 11; IPR2016-01104, Paper 15. Joinder is not proper for the reasons provided in AstraZeneca's respective oppositions to the motions for joinder, and for the reasons below. *See Wockhardt*, IPR2016-01029, Paper 8; *Sun Pharm. Indus.*, IPR2016-01104, Paper 12; *Aurobindo Pharma*, IPR2016-01117, Paper 8.

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