

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA U.S.A., INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2016-01117
Patent RE44,186

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. Introduction.....1

II. Procedural History Relevant to 35 U.S.C. § 315(b).....1

III. Aurobindo’s Untimely Petition Should Be Denied.....2

 A. Aurobindo’s Petition Is Time-Barred Under 35 U.S.C. § 315(b).....2

 B. Aurobindo’s Motion for Joinder Is Not Warranted3

IV. Conclusion6

TABLE OF AUTHORITIES

Page(s)

Cases

Atoptech, Inc. v. Synopsys, Inc.
IPR2015-00760, Paper 14 (PTAB July 21, 2015)3

Medtronic, Inc. v. Endotach LLC,
IPR2014-00695, Paper 18 (PTAB Sept. 25, 2014).....3

Microsoft Corp. v. Surfcast, Inc.,
IPR2014-00271, Paper 20 (PTAB June 13, 2014)4, 5

Samsung Electronics Co., Ltd. v. Arendi S.A.R.L.,
IPR2014-01142, Paper 11 (PTAB Oct. 2, 2014).....3, 5

St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.,
IPR2013-00258, Paper 29 (PTAB Oct. 16, 2013)6

Standard Innovation Corp. v. Lelo, Inc.,
IPR2014-00907, Paper 10 (PTAB Dec. 1, 2014)5

Teva Pharm. USA Inc. v. ViiV Healthcare Co.,
IPR2015-00550, Paper 11 (PTAB June 25, 2015)5

Statutes

35 U.S.C. § 3113

35 U.S.C. § 3133

35 U.S.C. § 314.....3

35 U.S.C. § 315(b) 1-5

35 U.S.C. § 315(c)3

Other Authorities

37 C.F.R. § 42.1(b)4

37 C.F.R. § 42.122(b)5

I. Introduction

Aurobindo's Petition for *inter partes* review ("IPR") is time-barred under 35 U.S.C. § 315(b), having been filed more than two years after Aurobindo was served with a Complaint alleging infringement of AstraZeneca's RE44,186 patent (the "RE'186 patent"). To avoid the § 315(b) bar, Aurobindo proposes joinder to instituted IPR2015-01340 (*Mylan Pharms. Inc. v. AstraZeneca AB*) (the "Mylan IPR"). Joinder is not warranted here, because Aurobindo'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 29, 2014, AstraZeneca served Aurobindo with a Complaint for infringement of the RE'186 patent based on Aurobindo's submission of an Abbreviated New Drug Application ("ANDA") to market a generic version of AstraZeneca's pharmaceutical product ONGLYZA[®]. **Ex. 2001** at 14, D.I. 1 (Complaint against Aurobindo filed May 23, 2014); *id.* at 15, D.I. 7 (Aurobindo served on May 29, 2014). More than two years after being served with the Complaint in the district court action, Aurobindo filed a Petition for IPR of the RE'186 patent and a motion to join the Mylan IPR. IPR2016-01117, Paper 1 at 68 (filed June 1, 2016), Paper 3.

The RE'186 patent at issue in Aurobindo'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 Aurobindo and Mylan. **Ex. 2001** at 17 (Remark entered Oct. 8, 2014). Trial is set for September 19, 2016, in Delaware District Court. **Ex. 2001** at 17-18 (Order entered Oct. 20, 2014).

Other defendants to the district court action similarly filed time-barred petitions for IPR and similarly requested joinder to the Mylan IPR. *See Wockhardt Bio AG v. AstraZeneca AB*, IPR2016-01029, Papers 1, 3; *Sun Pharm. Indus., Ltd. v. AstraZeneca AB*, IPR2016-01104, Papers 3, 4. Joinder is not proper for the reasons provided in AstraZeneca's respective oppositions to those motions for joinder and for the reasons below. *See Wockhardt*, IPR2016-01029, Paper 8; *Sun & Amneal*, IPR2016-01104, Paper 12; *Aurobindo*, IPR2016-01117, Paper 8.

III. Aurobindo's Untimely Petition Should Be Denied

A. Aurobindo's Petition Is Time-Barred Under 35 U.S.C. § 315(b)

There is no dispute that Aurobindo's Petition is time-barred. Aurobindo filed its Petition more than one year after it was served with a complaint alleging infringement of the RE'186 patent. *See IPR2016-01117*, Paper 1 at 16, n.2 (Petitioner acknowledging passage of over one year). The statute states:

An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.