

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.  
Petitioner,

v.

MERCK SHARP & DOHME CORP.  
Patent Owner.

U.S. Patent No. 7,326,708 to Cypes et al.

Issue Date: February 5, 2008

Title: Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor

*Inter Partes* Review No.: IPR2020-00040

**Petitioner's Reply to Patent Owner's Preliminary Response**

***Mail Stop "PATENT BOARD"***

Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TABLE OF CONTENTS**

I. INSTITUTION SHOULD NOT BE DENIED BASED ON §325(D)..... 1

    A. Petitioner's Asserted Grounds Were Not Considered during Prosecution (*Becton* Factors (a-e)).....1

    B. Additional Evidence and Facts Presented in the Petition Warrant Reconsideration of the Prior Art (*Becton* Factor (f)). .....4

II. §314(A) DOES NOT SUPPORT DENIAL OF THE PETITION .....5

III. THE PTAB SHOULD EVALUATE MERCK'S ANTEDATING EVIDENCE AFTER INSTITUTION .....7

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Acrux DDS Pty Ltd. v. Kaken Pharm. Co., Ltd.</i> , IPR2017-00190, Paper 12 (PTAB May 1, 2017) .....	7
<i>Agrinomix LLC v. Mitchell Ellis Products Inc.</i> , IPR2017-00525, Paper 8 (PTAB Jun. 14, 2017) .....	3, 4
<i>Alarm.com Inc. v. Vivint, Inc.</i> , IPR2015-01967, Paper 12 (PTAB Mar. 30, 2016) .....	3
<i>Amgen Inc. v. Alexion Pharms. Inc.</i> , IPR2019-00740, Paper 15 (PTAB Aug. 20, 2019).....	2
<i>Amneal Pharms. LLC et al. v. Almirall LLC</i> , IPR2019-00207, Paper 39 (PTAB Dec. 31, 2019) .....	8
<i>Apotex, Inc. v. UCB Biopharma, SPRL</i> , IPR2019-00400, Paper 17 (July 15, 2019) .....	1, 5
<i>Associated British Foods, PLC v. Cornell Research Foundation Inc.</i> , IPR2019-00578, Paper 25 (PTAB July 25, 2019).....	8
<i>Becton, Dickinson and Company v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) .....	4, 5
<i>Celltrion, Inc. v. Genentech, Inc.</i> , IPR2017-01373, Paper 16 (PTAB Dec. 1, 2017) .....	7
<i>Clim-A-Tech Indus., Inc. v. William A. Ebert</i> , IPR2017-01863, Paper 13 (PTAB Feb. 12, 2018).....	3
<i>Hyperbranched Medical Technology, Inc., v. Confluent Surgical, Inc.</i> , IPR2018-01097, Paper 14 (PTAB Nov. 14, 2018).....	2
<i>Pfizer Inc. v. Genetech, Inc.</i> , IPR2018-00300, Paper 13 (PTAB July. 9, 2018).....	2
<i>Polycom Inc. v. Directpacket Research, Inc.</i> , IPR2019-01233, Paper 14 (PTAB Nov. 5, 2019).....	8

*Quest USA Corp. v. PopSockets LLC*,  
IPR2018-00497, Paper 8 (PTAB Aug. 13, 2018).....8

*RJ Reynolds Vapor Co. v. Fontem Holdings I BV*,  
IPR2017-01642, Paper 10 (PTAB Jan. 16, 2018) .....3

*Sandoz Inc. v. Pharmacyclics LLC*,  
IPR2019-00865, Paper 8 (PTAB Sept. 26, 2019).....5, 6, 7, 8

*TRW Automotive US LLC v. Magna Electronics Inc.*,  
IPR2014-00261, Paper 19 (PTAB June 26, 2014) .....2

**Statutes**

35 U.S.C. §314(a) .....5, 6, 7, 8

35 U.S.C. §325(d) .....1, 2, 3, 5

**I. INSTITUTION SHOULD NOT BE DENIED BASED ON §325(D)**

**A. Petitioner's Asserted Grounds Were Not Considered During Prosecution (*Becton Factors (a-e)*).**

There is no dispute that the Examiner never put forth **any** prior art rejection during prosecution of the '708 patent, including the grounds advanced in the Petition. Instead, Merck's entire argument is premised on three facts: (1) an IDS listing the '871 patent and WO '498; (2) a hurried account of WO '498 in the specification of the '708 patent; and (3) Merck's speculations as to the Examiner's actions. Even Merck concedes that the Examiner did not initial the listing of WO '498 on the IDS. POPR at 17, EX1010 at 157. Absent the Examiner's initials, as the IDS explicitly states, WO '498 was not considered. *Id.* ("Initial if reference considered."). To address any confusion, in minutes, Merck could have resubmitted an IDS with WO '498, filed an RCE with an IDS, or simply called the Examiner. Merck did not. Instead, without explanation, Merck asks that its inaction be excused and institution of Mylan's petition be denied. Finally, as Merck admits, the specification of the '708 patent discusses WO '498 but not the '871 patent. POPR 14-15. It is not incumbent upon the Examiner to link the '871 patent and WO '498.

"The Board has consistently declined to exercise its discretion under §325(d) based on the mere citation of references in an IDS that were not applied by the Examiner." *Apotex, Inc. v. UCB Biopharma, SPRL*, IPR2019-00400, Paper 17 at 24 (July 15, 2019); *Amgen Inc. v. Alexion Pharmaceuticals Inc.*, IPR2019-00740,

# 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.