

Paper No. \_\_\_\_\_

Filed on behalf of Apotex Inc.  
By: Kenneth J. Burchfiel  
Grant S. Shackelford  
Sughrue Mion, PLLC  
2100 Pennsylvania Ave., NW  
Washington, DC 20037  
Telephone: 202-293-7060  
Facsimile: 202-293-7860  
email: kburchfiel@sughrue.com  
gshackelford@sughrue.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

APOTEX INC.  
Petitioner

v.

MERCK & CO., INC.  
Patent Owner

---

Case IPR2015-00419  
Patent No. 5,691,336

---

**ATTN: CHIEF ADMINISTRATIVE PATENT JUDGE**

**APOTEX PETITION UNDER 37 CFR § 41.3  
SUGGESTING RECONSIDERATION BY  
AN EXPANDED PANEL UNDER S.O.P. 1**

## TABLE OF CONTENTS

	<b>Page</b>
TABLE OF AUTHORITIES .....	II
I. INTRODUCTION .....	1
II. PROCEDURAL BACKGROUND.....	1
III. REASONS WHY THE REQUEST FOR RECONSIDERATION SHOULD BE HEARD BY AN EXPANDED PANEL .....	1
A. The Decision Denying Institution .....	1
B. The Merits Panel Decision Conflicts With Other Board Decisions Concerning the Legal Standard for Obviousness.....	2
1. The merits Panel’s “lead compound” analysis is incorrect .....	2
2. The merits Panel’s decision conflicts with Ex parte Dong.....	3
3. The merits Panel’s decision conflicts with Ex parte Cao .....	5
C. The Correct Legal Standard for Obviousness of Chemical Compounds Is An Issue of Exceptional Importance.....	5
IV. PAYMENT OF FEE.....	6

## TABLE OF AUTHORITIES

### CASES

<i>Aventis Pharma Deutschland GmbH v. Lupin, Ltd.</i> , 499 F.3d 1293 (Fed. Cir. 2007).....	5
<i>Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.</i> , 619 F.3d 1346 (Fed. Cir. 2010).....	3, 4
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008).....	5
<i>Ex parte Cao</i> , Appeal No. 2010-004081 (BPAI Sept. 19, 2011) .....	5
<i>Ex parte Dong</i> , Appeal No. 2011-0100471 (PTAB Jan. 28, 2013).....	3, 4
<i>In re Dillon</i> , 919 F.2d 688 (Fed. Cir. 1990) ( <i>en banc</i> ) .....	2, 5
<i>Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.</i> , 678 F.3d 1280 (Fed. Cir. 2012).....	4

### REGULATIONS

37 C.F.R. § 42.71(c).....	2
37 CFR § 41.3 .....	1
37 CFR § 41.3(c).....	6
37 CFR § 41.3(e).....	1
37 CFR § 41.20 .....	6

## **I. INTRODUCTION**

Pursuant to 37 CFR § 41.3 and Standard Operating Procedure 1.III.C (Rev. 14, “SOP 1”) Apotex Inc. (“Petitioner”) respectfully suggests that its Request for Reconsideration of the Decision Denying Institution of *Inter Partes* Review (Paper 14) be heard by an expanded panel. Because the merits Panel used an obviousness standard that conflicts with earlier Board decisions and *en banc* Federal Circuit precedent, hearing by an expanded Panel is needed to eliminate uncertainty as to the proper legal standard for obviousness of chemical compounds in proceedings before the Board.

## **II. PROCEDURAL BACKGROUND**

This Petition under 37 CFR § 41.3 Suggesting Reconsideration By An Expanded Panel Under S.O.P. 1 is filed concurrently with a Request for Reconsideration and therefore is timely under 37 CFR § 41.3(e).

## **III. REASONS WHY THE REQUEST FOR RECONSIDERATION SHOULD BE HEARD BY AN EXPANDED PANEL**

### **A. The Decision Denying Institution**

In denying institution of *inter partes* review, the merits Panel used an obviousness test that is contrary to both PTAB and *en banc* Federal Circuit precedent to hold that Petitioner did not establish a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. For the reasons stated in the concurrently-filed Petitioner Request for Reconsideration

Under 37 CFR § 42.71(c), this decision is based on legal error and thus constitutes an abuse of discretion warranting reconsideration.

The merits Panel applied a rigid and unduly restrictive “lead compound” analysis that has been specifically rejected by earlier PTAB decisions as being inconsistent with the structural obviousness standard required by *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990) (*en banc*).

**B. The Merits Panel Decision Conflicts With Other Board Decisions Concerning the Legal Standard for Obviousness**

The obviousness analysis applied by the merits Panel conflicts with earlier Board decisions, which have consistently stated that the “lead compound” analysis applied by the merits Panel has not superseded the “structural obviousness” standard for *prima facie* obviousness of chemical compounds required by *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (*en banc*). Consideration by an expanded Panel is thus “necessary to secure and maintain uniformity of the Board’s decisions.” SOP 1(III)(A)(2). Review by an expanded Panel is particularly important, because merits Panel decisions denying IPR are not subject to review in the Federal Circuit or by the Board.

*1. The merits Panel’s “lead compound” analysis is incorrect*

The merits Panel’s decision is based on three incorrect legal conclusions, which conflict with other Board decisions and Federal Circuit precedent:

# 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.