

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

MERCK SHARP & DOHME CORP.,  
Patent Owner.

---

Case No. IPR2020-00040  
U.S. Patent No. 7,326,708

---

**PATENT OWNER'S PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

INTRODUCTION ..... 1

BACKGROUND ..... 4

    A.    Sitagliptin and the '708 Patent ..... 4

    B.    '708 Patent Prosecution History..... 5

    C.    Summary of Mylan's Grounds and Asserted Art..... 7

    D.    Related District Court Litigation..... 10

ARGUMENT ..... 13

I.    The Board Should Exercise Its Discretion Pursuant to §§ 325(d) and 314(a) to Deny Institution..... 13

    A.    The Board Should Reject Mylan's Petition Under § 325(d) as a Mere Rehash of the Same Prior Art and Arguments Previously Presented to the Office. .... 13

    B.    The Board Should Exercise Its Discretion and Decline to Institute Trial Under § 314(a)..... 23

        1.    Instituting Trial on Mylan's Petition Would be an Inefficient Use of the Board's Limited Resources ..... 24

        2.    The Board Should Deny Institution Rather Than Institute Trial on Clearly Meritless Grounds ..... 31

II.   Mylan's Petition Fails Because It Does Not Address the Claimed 1:1 Stoichiometric Ratio of Sitagliptin and Phosphoric Acid ..... 46

    A.    Mylan Does Not Argue that WO '498 or the '871 Patent Expressly Disclose the Claimed 1:1 Salt ..... 48

    B.    Mylan Does Not Explain How WO '498 or the '871 Patent Inherently Disclose the Claimed 1:1 DHP Salt..... 50

    C.    Mylan's Obviousness Grounds Incorporate Its Defective Anticipation Arguments and Should be Denied ..... 52

CONCLUSION ..... 54

**TABLE OF AUTHORITIES**

*Arendi S.A.R.L. v. Apple Inc.*,  
832 F.3d 1355 (Fed. Cir. 2016) .....51

*Constant v. Advanced Micro-Devices, Inc.*,  
848 F.2d 1560 (Fed. Cir. 1988) .....43

*Cooper v. Goldfarb*,  
154 F.3d 1321 (Fed. Cir. 1998) .....34, 35

*Dynamic Drinkware LLC v. Nat’l Graphics, Inc.*,  
800 F.3d 1375 (Fed. Cir. 2015) .....33

*Harmonic Inc. v. Avid Tech, Inc.*,  
815 F.3d 1356 (Fed. Cir. 2016) .....13, 31

*In re Steed*, 802 F.3d 1311 (Fed. Cir. 2015) .....32, 34

*Neptune Generics, LLC v. Eli Lilly & Co.*,  
921 F.3d 1372 (Fed. Cir. 2019) .....27

*Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*,  
851 F.3d 1270 (Fed. Cir. 2017) .....46

*Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365 (2018).....13

*Organik Kimya AS v. Rohm & Haas Co.*,  
873 F.3d 887 (Fed. Cir. 2017) .....52

*Par Pharm., Inc. v. TWI Pharm., Inc.*,  
773 F.3d 1186 (Fed. Cir. 2014) .....47

*PersonalWeb Techs., LLC v. Apple, Inc.*,  
917 F.3d 1376 (Fed. Cir. 2019) .....47

*PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*,  
491 F.3d 1342 (Fed. Cir. 2007) .....43

*Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*,  
748 F.2d 645 (Fed. Cir. 1984) .....42, 43

<i>SAS Institute, Inc. v. Iancu</i> , 138 S. Ct. 1348 (2018).....	24
<i>Sjolund v. Musland</i> , 847 F.2d 1573 (Fed. Cir. 1988) .....	43
<i>St. Regis Mohawk Tribe v. Mylan Pharm. Inc.</i> , 896 F.3d 1322 (Fed. Cir. 2018) .....	13
<i>XY, LLC v. Trans Ova Genetics, L.C.</i> , 890 F.3d 1282 (Fed. Cir. 2018) .....	26
<i>Alarm.com Inc. v. Vivint, Inc.</i> , IPR2015-01967, Paper 12 (P.T.A.B. Mar. 30, 2016) .....	21
<i>Amgen Inc. v. Alexion Pharmaceuticals Inc.</i> , IPR2019-00740, Paper 15 (P.T.A.B. Aug. 20, 2019).....	21, 22, 23
<i>Amneal Pharmaceuticals LLC v. Alkermes Pharma Ireland Limited</i> , IPR2018-00943, Paper 8 (P.T.A.B. Nov. 7, 2018).....	22
<i>Apple Inc. v. SightSound Techs., LLC</i> , CBM2013-00021, Paper 13 (P.T.A.B. Oct. 8, 2013) .....	27
<i>Aquestive Therapeutics, Inc., v. Neurelis, Inc.</i> , IPR2019-00450, Paper 8 (P.T.A.B. Aug. 1, 2019).....	18
<i>Arctic Cat, Inc. v. Polaris Indus. Inc.</i> , IPR2014-01427, Paper 58 (P.T.A.B. Feb. 4, 2016).....	48
<i>Associated British Foods plc v. Cornell Research Foundation, Inc.</i> , IPR2019-00578, Paper 25 (P.T.A.B. July 25, 2019) .....	44
<i>Becton, Dickinson &amp; Co. v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) .....	14, 20
<i>Biodelivery Scis. Int’l v. Aquestive Therapeutics, Inc.</i> , IPR2015-00165, Paper 91 (P.T.A.B. Feb. 7, 2019).....	32
<i>C.R. Bard, Inc. v. Med. Components, Inc.</i> , IPR2015-01660, Paper 9 (P.T.A.B. Feb. 9, 2016).....	51

<i>Cambrios Film Sols. Corp. v. C3Nano Inc.</i> , IPR2019-00709, Paper 15 (P.T.A.B. Aug. 26, 2019).....	51
<i>Chevron Oronite Co. LLC, v. Infineum USA L.P.</i> , IPR2018-00923, Paper 9 (P.T.A.B. Nov. 7, 2018).....	32, 44
<i>Clim-A-Tech Ind., Inc. v. William A. Ebert</i> , IPR2017-01863, Paper 13 (P.T.A.B. Feb. 12, 2018).....	21
<i>Comcast Cable Commc'ns, LLC v. Veveo, Inc.</i> , IPR2017-00932, Paper 10 (P.T.A.B. Sept. 7, 2017).....	46, 51
<i>Corning Inc. v. DSM IP Assets B.V.</i> , IPR2013-00053, Paper 66 (P.T.A.B. May 1, 2014) .....	40
<i>Cosmax Co. v. AmorePacific Corp.</i> , IPR2018-01516, Paper 8 (P.T.A.B. Feb. 20, 2019).....	16
<i>Cultec, Inc. v. StormTech LLC</i> , IPR2017-00777, Paper 7 (P.T.A.B. Aug. 22, 2017).....	16
<i>Deeper, UAB v. Vexilar, Inc.</i> , IPR2018-01310, Paper 7 (P.T.A.B. Jan. 24, 2019) .....	32, 44
<i>Digital Check Corp. v. e-ImageData Corp.</i> , IPR2017-00178, Paper 6 (P.T.A.B. Apr. 25, 2017) .....	22, 23
<i>E-One, Inc. v. Oshkosh Corp.</i> , IPR2019-00161, Paper 16 (P.T.A.B. May 15, 2019) .....	24, 25, 28, 29
<i>Fortinet Inc. v. British Telecomms. Pub. Ltd.</i> , IPR2019-01326, Paper 8 (P.T.A.B. Jan. 7, 2020) .....	19
<i>Fox Factory, Inc. v. SRAM, LLC</i> , IPR2016-01876, Paper 8 (P.T.A.B. Apr. 3, 2017) .....	23
<i>FreeBit AS v. Bose Corp.</i> , IPR2017-01307, Paper 8 (P.T.A.B. Nov. 14, 2017).....	32, 45
<i>General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017).....	29

# 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.