

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS  
(IRELAND) DESIGNATED ACTIVITY COMPANY,  
Patent Owners.

---

Case IPR2018-00272  
Patent 9,393,208

---

**PATENT OWNERS' RESPONSE**

*37 C.F.R. § 42.10*

## TABLE OF CONTENTS

	Page
I. BACKGROUND .....	2
A. The '208 Patent and Vimovo® .....	2
1. Technical Background .....	2
2. The '208 Patent .....	8
a. Dr. Plachetka and His Team Conceived Of and Reduced To Practice The Invention Claimed In The '208 Patent By June 25, 2007.....	9
b. Illustrative Claim .....	13
B. District Court Litigations Regarding The Vimovo® Patents.....	15
II. SUMMARY OF ARGUMENT.....	17
III. MYLAN'S PETITION SHOULD BE TERMINATED .....	19
IV. THE OPINIONS OF MYLAN'S EXPERT DECLARANTS SHOULD BE AFFORDED LITTLE WEIGHT .....	20
V. MYLAN HAS FAILED TO ESTABLISH THAT THE '285 PATENT OR THE EC-NAPROSYN LABEL ARE PRIOR ART .....	21
A. Mylan Cannot Show That The '285 Patent Is § 102(e) Prior Art.....	21
B. The EC-NAPROSYN® Label Does Not Qualify As Prior Art.....	25
1. Petitioner Failed To Establish That Exhibit 1009 Is A Publicly Available Printed Publication.....	25
2. Petitioner Failed To Establish That Exhibit 1009 Predates The Invention Date.....	30
VI. MYLAN HAS FAILED TO PROVE CLAIMS 1-7 ARE INHERENTLY ANTICIPATED BY THE '285 PATENT .....	30
VII. MYLAN HAS FAILED TO PROVE CLAIMS 1-7 ARE OBVIOUS IN LIGHT OF THE '285 PATENT .....	34
A. The '285 Patent Cannot Not Be Used To Render the '208 Patent Obvious .....	35
B. The '285 Patent Does Not Render The '208 Patent Inherently Obvious .....	37

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
VIII. MYLAN HAS FAILED TO PROVE CLAIMS 1-7 ARE OBVIOUS IN LIGHT OF THE '285 PATENT, EC-NAPROSYN LABEL, AND HOWDEN 2005.....	40
1.    '285 patent (Exhibit 1005).....	40
2.    EC-Naprosyn® Label (Exhibit 1009).....	41
3.    Howden 2005 (Exhibit 1006).....	41
4.    Mylan's Ground III Fails .....	45
IX. OBJECTIVE INDICIA OF NONOBVIOUSNESS DEMONSTRATE THE PATENTABILITY OF THE CLAIMED INVENTIONS .....	47
A.    Long-Felt Need.....	48
B.    Teaching Away and Surprising and Unexpected Results .....	50
C.    Skepticism .....	52
X. CONCLUSION.....	53

## TABLE OF AUTHORITIES

	Page(s)
<b>Cases</b>	
<i>Ariosa Diagnostics, Inc. v. Illumina, Inc.</i> , IPR2014-01093, Paper 69 (P.T.A.B. Jan. 7, 2016) .....	22
<i>Blackberry Corp. v. MobileMedia Ideas, LLC</i> , IPR2013-00036, Paper 65 .....	19, 20
<i>Bruckelmyer v. Ground Heaters, Inc.</i> , 445 F.3d 1374 (Fed. Cir. 2006) .....	27
<i>Burroughs Wellcome Co. v. Barr Labs., Inc.</i> , 40 F.3d 1223 (Fed. Cir. 1994) .....	9
<i>Celltrion, Inc. v. Biogen, Inc.</i> , IPR2016-01614, Paper 65 (P.T.A.B. Feb. 21, 2018).....	29
<i>Cohesive Techs., Inc. v. Waters Corp.</i> , 543 F.3d 1351 (Fed. Cir. 2008) .....	37
<i>Cooper v. Goldfarb</i> , 154 F.3d 1321 (Fed. Cir. 1998) .....	9
<i>In re Costello</i> , 717 F.2d 1346 (Fed. Cir. 1983) .....	22
<i>In re DeBaun</i> , 687 F.2d 459 (C.C.P.A. 1982) .....	23
<i>Dow Chem. Co. v. Astro-Valcour, Inc.</i> , 267 F.3d 1334 (Fed. Cir. 2001) .....	10
<i>Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015) .....	22
<i>Enzo Biochem, Inc. v. Applera Corp.</i> , 599 F.3d 1325 (Fed. Cir. 2010) .....	19
<i>Fox Grp., Inc. v. Cree, Inc.</i> , 700 F.3d 1300 (Fed. Cir. 2012) .....	9, 10

**TABLE OF AUTHORITIES**  
 (continued)

	<b>Page(s)</b>
<i>Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH,</i> IPR2016-00649, Paper 10 (P.T.A.B. Sept. 1, 2016).....	28
<i>Harmonic Inc. v. Avid Tech., Inc.,</i> 815 F.3d 1356 (Fed. Cir. 2016) .....	25
<i>In re Haruna,</i> 249 F.3d 1327 (Fed. Cir. 2001) .....	50
<i>Honeywell International Inc. v. Mexichem Amanco Holding S.A. DE C.V.,</i> 865 F.3d 1348 (Fed. Cir. 2017) .....	38, 39
<i>In re Huai-Hung Kao,</i> 639 F.3d 1057 (Fed. Cir. 2011) .....	48
<i>Kyocera Wireless Corp. v. ITC,</i> 545 F.3d 1340 (Fed. Cir. 2008) .....	27
<i>In re Lister,</i> 583 F.3d 1307 (Fed. Cir 2009) .....	27
<i>Microsoft Corp. v. Corel Software, LLC,</i> IPR2016-01300, Paper 13 (P.T.A.B. Jan. 4, 2017) .....	28
<i>Microsoft Corp. v. IpLearn-Focus, LLC,</i> IPR2015-00097, Paper 11 (P.T.A.B. Mar. 26, 2015) .....	20
<i>Monsanto Tech. LLC v. E.I. DuPont de Nemours &amp; Co.,</i> 878 F.3d 1336 (Fed. Cir. 2018) .....	37
<i>Mylan Pharm. Inc. v. Boehringer Ingelheim Intl. GMBH,</i> IPR2016-01566, Paper 15 (P.T.A.B. Feb. 3, 2017).....	27, 28
<i>Netgear, Inc. v. Ruckus Wireless, Inc.,</i> 5 F. Supp. 3d 592 (D. Del. 2013).....	36

# 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.