

Filed: August 24, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.,

Patent Owners

U.S. Patent No. 9,220,698 to Ault *et al.*

Inter Partes Review IPR2017-01995

Petition for *Inter Partes* Review of U.S. Patent No. 9,220,698

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. MANDATORY NOTICES	1
A. Real Parties-In-Interest Under 37 C.F.R. § 42.8(b)(1).....	1
B. Related Matters Under 37 C.F.R. § 42.8(b)(2)	1
C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)	2
D. Service Information Under 37 C.F.R. § 42.8(b)(4).....	2
III. GROUNDS FOR STANDING (37 C.F.R. §§ 42.101 AND 42.104)	3
IV. IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED (37 C.F.R. § 42.22(A) AND 37 C.F.R. § 42.104(B)).....	3
V. THRESHOLD REQUIREMENT FOR <i>INTER PARTES</i> REVIEW	4
VI. STATEMENT OF REASONS FOR THE RELIEF REQUESTED	4
A. Summary of the Argument.....	4
B. Level of Ordinary Skill in the Art	7
C. The '698 Patent and Its Prosecution.....	8
1. NSAID Gastropathy	8
2. Specification of the '698 Patent.....	8
3. The '698 Patent Prosecution	14
D. Claim Construction (37 C.F.R. §§ 42.100(b), 42.104(b)(3)).....	15
1. “Target” Means “With The Goal of Obtaining”	16
E. Scope and Content of the Prior Art	19
1. PK/PD Overview.....	19
2. References Disclosing Combined Naproxen- Esomeprazole Formulations.....	21
a. '285 Patent	21
b. '907 Patent	24
c. Hochberg 2008.....	25

d.	Goldstein 2008.....	26
e.	Hassan-Alin 2005	27
3.	References Disclosing the PK/PD of Immediate-Release PPIs	28
a.	Howden 2005.....	28
b.	Zegerid [®] Label.....	29
4.	References Disclosing the Pharmacokinetics of Naproxen.....	31
a.	EC-Naprosyn [®] Label	31
b.	Khosravan 2006.....	32
c.	Jung 1994.....	33
d.	Davies 1997	33
F.	Ground 1: All Claims of the '698 Patent Are Anticipated by the '285 Patent.....	34
1.	The Method of Claim 1 Is Anticipated by the '285 Patent.....	34
a.	The '285 patent disclosed the drug formulation in claim 1	34
b.	The PK/PD elements in claim 1 are inherent in the formulation	36
2.	The dependent claims are anticipated by the '285 patent.....	40
a.	Dependent claim 2 is anticipated.....	40
b.	Dependent claims 3 and 4 are anticipated	40
c.	Dependent claims 5-7 are anticipated.....	41
G.	Ground 2: All Claims of the '698 Patent Are Obvious Over the '285 Patent.....	43
H.	Ground 3: All Claims of the '698 Patent Are Obvious Over the '285 patent in View of the EC-Naprosyn [®] Label and Howden 2005	48
1.	The Method of Claim 1 Is Obvious Over the '285 patent in View of the EC-Naprosyn [®] Label and Howden 2005.....	48
a.	The EC-Naprosyn [®] label disclosed the PK elements for naproxen	49

b.	Howden 2005 disclosed the PK elements for esomeprazole	52
c.	Howden 2005 disclosed the PD element	57
2.	The dependent claims are obvious over the '285 patent in view of the EC-Naprosyn [®] label and Howden 2005	58
a.	Dependent claim 2 is obvious.....	58
b.	Dependent claims 3 and 4 are obvious	59
c.	Dependent claims 5-7 are obvious	59
I.	No Secondary Considerations Support Nonobviousness.....	59
1.	There Are No Unexpected Results	60
2.	The '698 Patent Satisfied No Long-Felt But Unmet Need.....	62
3.	There Was No Industry Skepticism	63
4.	Copying by Generic Drug Makers Is Irrelevant	63
VII.	CONCLUSION.....	63

TABLE OF AUTHORITIES

Page

CASES

<i>Atlas Powder Co. v. Ireco, Inc.</i> , 190 F.3d 1342 (Fed. Cir. 1999)	38
<i>Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.</i> , 713 F.3d 1369 (Fed. Cir. 2013)	63
<i>Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.</i> , 246 F.3d 1368 (Fed. Cir. 2001)	4, 37
<i>Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.</i> , 752 F.3d 967 (Fed. Cir. 2014)	62
<i>Cuozzo Speed Techs., LLC v. Lee</i> , No. 15-446, 136 S. Ct. 2131 (2016)	15
<i>Eli Lilly & Co. v. Barr Labs., Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001)	37
<i>Ex parte DesOrmeaux</i> , 25 U.S.P.Q. 2d 2040 (Bd. Pat. App. & Inter. 1992)	22
<i>In re Am. Acad. of Sci. Tech. Ctr.</i> , 367 F.3d 1359 (Fed. Cir. 2004)	16
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Litigation</i> , 676 F.3d 1063 (Fed. Cir. 2012)	14, 15
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	45
<i>King Pharmaceuticals, Inc. v. Eon Labs, Inc.</i> , 616 F.3d 1267 (Fed. Cir. 2010)	45, 46
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	48
<i>Millennium Pharm., Inc. v. Sandoz Inc.</i> , 862 F.3d 1356 (Fed. Cir. 2017)	46

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.