

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HIKMA PHARMACEUTICALS USA INC.,
HIKMA PHARMACEUTICALS PLC,
Petitioner,

v.

AMARIN PHARMACEUTICALS IRELAND LIMITED,
Patent Owner.

Case IPR2022-00215
Patent 8,642,077 B2
Issued: February 4, 2014

Title: STABLE PHARMACEUTICAL
COMPOSITION AND METHODS OF USING SAME

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

	Page
LIST OF EXHIBITS	vii
I. INTRODUCTION	1
II. MANDATORY NOTICES	3
III. REQUIREMENTS FOR REVIEW	4
IV. THE '077 PATENT	5
V. LEVEL OF ORDINARY SKILL	7
VI. TECHNICAL BACKGROUND	8
VII. CLAIM CONSTRUCTION	10
VIII. PRIOR-ART REFERENCES	13
A. Yokoyama I	14
B. Mori	14
C. Yokoyama II	15
D. Satoh	16
E. Grimsgaard	16
IX. ANALYSIS OF GROUNDS FOR TRIAL	17
A. Grounds based on Yokoyama I	17
1. <u>Ground A.1</u> : Yokoyama I anticipates claims 1, 8, and 19	17
a. Independent claim 1	17
b. Dependent claim 8	25
c. Dependent claim 19	27
2. <u>Ground A.2</u> : Dependent claim 8 would have been obvious over Yokoyama I in view of Satoh.	28
3. <u>Ground A.3</u> : Dependent claims 14–18 would have been obvious over Yokoyama I in view of Grimsgaard.	31
a. Dependent claims 14, 16, 17	31
b. Dependent claims 15 and 18	34
B. Grounds based on Mori and Yokoyama II	34
1. <u>Ground B.1</u> : Claims 1, 8, and 19 would have been obvious over Mori in view of Yokoyama II.	34

a.	Independent claim 1	34
b.	Dependent claim 8	40
c.	Dependent claim 19	42
2.	<u>Ground B.2</u> : Dependent claim 8 would have been obvious over Mori in view of Yokoyama II and Satoh.	42
3.	<u>Ground B.3</u> : Dependent claims 14–18 would have been obvious over Mori in view of Yokoyama II and Grimsgaard.	44
a.	Dependent claims 14, 16, 17	44
b.	Dependent claims 15 and 18.....	46
C.	There are no secondary considerations of nonobviousness.	46
1.	The claimed method does not produce unexpected results.	47
2.	Patent Owner’s Vascepa lacks a nexus to the claims.	55
3.	Any alleged secondary considerations would be discounted by the blocking effect of existing and expected patents.	56
X.	DISCRETIONARY FACTORS.....	57
A.	The Board should not deny review under § 314(a).....	57
1.	<i>Fintiv</i> factors 2–4 and 6 strongly favor institution.	58
2.	The remaining <i>Fintiv</i> factors do not warrant denial.	59
B.	The Board should not deny review under § 325(d).	60
XI.	CONCLUSION.....	62
	CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION.....	63
	CERTIFICATE OF SERVICE	64

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Acorda Therapeutics, Inc. v. Roxane Labs., Inc.</i> , 903 F.3d 1310 (Fed. Cir. 2018)	57
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	60
<i>Alcon Research, Ltd. v. Apotex Inc.</i> , 687 F.3d 1362 (Fed. Cir. 2012)	30
<i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , 449 F. Supp. 3d 967 (D. Nev. 2020).....	35, 37
<i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 1:20-cv-01630 (D. Del.).....	3
<i>Amgen Inc. v. Alexion Pharm., Inc.</i> , IPR2019-00740, Paper 15 (PTAB Aug. 30, 2019).....	61
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....	57, 59
<i>Asyst Techs., Inc. v. Emtrak, Inc.</i> , 544 F.3d 1310 (Fed. Cir. 2008)	52
<i>Atlas Powder Co. v. Ireco Inc.</i> , 190 F.3d 1342 (Fed. Cir. 1999)	26
<i>Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.</i> , 246 F.3d 1368 (Fed. Cir. 2001)	25, 26, 40
<i>ClearValue, Inc. v. Pearl River Polymers, Inc.</i> , 668 F.3d 1340 (Fed. Cir. 2012)	23
<i>In re Cruciferous Sprout Litig.</i> , 301 F.3d 1343 (Fed. Cir. 2002)	26

<i>In re Dillon</i> , 919 F.2d 688 (Fed. Cir. 1990)	41
<i>Eli Lilly & Co. v. Perrigo Co.</i> , 718 F. App'x 953 (Fed. Cir. 2017)	48
<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	51, 52
<i>Gen. Hosp. Corp. v. Sienna Biopharmaceuticals, Inc.</i> , 888 F.3d 1368 (Fed. Cir. 2018)	32, 44
<i>Hoffmann-La Roche Inc. v. Apotex Inc.</i> , 748 F.3d 1326 (Fed. Cir. 2014)	30
<i>Inc. v. Netlist, Inc.</i> , IPR2020-01421, Paper 10 (PTAB Mar. 16, 2021)	59
<i>Ineos USA LLC v. Berry Plastics Corp.</i> , 783 F.3d 865 (Fed. Cir. 2015)	23
<i>Kao Corp. v. Unilever U.S., Inc.</i> , 441 F.3d 963 (Fed. Cir. 2006)	50
<i>In re Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	41, 51
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009)	41
<i>Lego Sys., Inc. v. MQ Gaming LLC</i> , IPR2020-01445, Paper 12 (PTAB Feb. 16, 2021)	59
<i>McNeil-PPC, Inc. v. L. Perrigo Co.</i> , 337 F.3d 1362 (Fed. Cir. 2003)	48
<i>Medichem, S.A. v. Rolabo, S.L.</i> , 353 F.3d 928 (Fed. Cir. 2003)	23
<i>Merck & Co. v. Teva Pharm. USA, Inc.</i> , 395 F.3d 1364 (Fed. Cir. 2005)	30, 43

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.