IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC. Petitioner,

V.

SENJU PHARMACEUTICAL CO., LTD. Patent Owner.

U.S. Patent No. 8,877,168 to Higashiyama
Issue Date: November 4, 2014
Title: Aqueous Liquid Preparations and Light-Stabilized Aqueous Liquid
Preparations

Inter Partes Review No.: IPR2016-01163

Petition for *Inter Partes* Review of U.S. Patent No. 8,877,168 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450



TABLE OF CONTENTS

I.	INTRODUCTION						
II.	OVERVIEW						
III.	STANDING (37 C.F.R. § 42.104(a)); PROCEDURAL STATEMENTS						
IV.	MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))	3					
	 B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))	4					
	C. Designation of Lead and Back-Up Counsel and Service (37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4))	4					
V.	STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a))						
VI.	THE '168 PATENT AND CLAIM CONSTRUCTION	5					
VII.	PERSON OF ORDINARY SKILL IN THE ART ("POSA")						
VIII.	IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))	6					
IX.	Invalidity analysis						
	 A. The Scope and Content of the Prior Art. 1. Bepotastine Besilate was Known as Having Good Properties and was Considered Suitable for Ophthalmic Preparations. 						
	a) Tanabe Press Release ("Tanabe") (EX1008)						
	 Adding Excipients, Including a Tonicity Agent, in Aqueous Liquid Preparations was Common	9					
	20th Ed. ("Hecht") (EX1005)	10 12					



В.	Ground 1: Claims 1-14 and 16-30 are Obvious over Tanabe in						
	view of Yanni						
	1.						
		be and Yanni together teach a bepotastine					
			besil	ate ophthalmic formulation	14		
		b)	Yanr	ni teaches "a light-stabilizing effective			
		ant" of water-soluble metal chloride	15				
		c)	A PC	OSA would have been motivated to combine			
			Tanabe and Yanni				
			(1)	Tanabe provides motivation to prepare an			
				ophthalmic formulation, which Yanni			
				provides	18		
			(2)	A POSA would have conducted routine			
				testing to determine the appropriate dose	18		
			(3)	Using sodium chloride and adjusting the			
				amount would have been obvious	19		
			(4)	Yanni discloses commonly used additives,			
				thus combining it with Tanabe according to			
				known methods would have yielded			
				predictable results			
	2. Independent Claim 16						
	3.	Independent Claim 23					
	4.		Dependent Claims 2 and 14				
	5.	-		Claims 3, 17, and 24			
	6.			Claim 4			
	7.	-		Claims 5-7, 18, 19, 25			
	8.	-		Claims 8-10, 20-22, 26-28			
	9.			Claims 11 and 12			
		,		ni teaches "an eye drop"	31		
				g Yanni's formulation for "a nasal drop"			
				d have been obvious			
	10.	_	ependent Claim 13				
_	11.			Claims 29 and 30	33		
C.	Ground 2: Claims 1-14 and 16-30 are Obvious over Tanabe in						
	1.	-		t Claim 1	34		
				be and Hecht together teach a bepotastine	2 -		
				ate ophthalmic formulation	36		
		/		at teaches "a light-stabilizing effective			
			amoi	int" of water-soluble metal chloride	37		



		,	OSA would have been motivated to combine	
		Tan	abe and Hecht	38
		(1)	Tanabe provides motivation to prepare an	
			ophthalmic formulation and Hecht provides	
			a conventional ophthalmic formulation	39
		(2)	A POSA would have conducted routine	
			testing to determine the appropriate dose	40
		(3)	Using sodium chloride and adjusting the	
		` '	amount would have been obvious	41
		(4)	Hecht discloses commonly used additives,	
		()	thus combining it with Tanabe according to	
			known methods would have yielded	
			predictable results	42
	2.	Independe	ent Claim 16	
	3.		ent Claim 23	
	4.	_	t Claims 2 and 14	
	5.		t Claims 3, 17, and 24	
	6.		t Claim 4	
	7.		t Claims 5-7, 18, 19, and 25	
	8.	-	t Claims 8-10, 20-22, and 26-28	
	9.		t Claims 11 and 12	
			cht teaches "an eye drop"	
			ng Hecht's formulation for "a nasal drop"	
			ald have been obvious	53
	10.		t Claim 13	
	11.		t Claims 29 and 30	
D.	Obje	-	a of Nonobviousness	
	1.		ected Results Over the Closest Prior Art	
			e range disclosed by the prior art is within the	
		•	med ranges and thus would have the same	
			perties	57
		1 1	OSA would have expected light-stabilizing	
		•	ects	59
		c) The	e alleged unexpected results are not	
		,	nmensurate in scope with the claim	60
	2.		ective Indicia	
COl	NCLUS	ION		63



X.

TABLE OF AUTHORITIES

	Page(s)
CASES	
Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294 (Fed. Cir. 2001)	1
Alcon Research, Ltd. v. Apotex Inc., 687 F.3d 1362 (Fed. Cir. 2012)	passim
Allergan Inc. v. Sandoz, Inc., 726 F.3d 1286 (Fed. Cir. 2013)	56
Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342 (Fed. Cir. 1999)	16
Bausch & Lomb Incorporated et al. v Apotex Inc. et al., 1:15-cv-03879 (D.N.J.)	4
Bausch & Lomb Incorporated et al. v Micro Labs USA, Inc. et al., No. 1:15-cv-03113 (D.N.J.)	4
Hoffmann-La Roche Inc. v. Apotex Inc., 748 F.3d 1326 (Fed. Cir. 2014)	61
<i>In re Aller</i> , 220 F.2d 454 (C.C.P.A. 1955)	passim
In re Applied Materials, Inc., 692 F.3d 1289 (Fed. Cir. 2012)	20
In re Baxter Travenol Labs., 952 F.2d 388 (Fed. Cir. 1991)	15, 37
<i>In re Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	56
<i>In re Peterson</i> , 315 F.3d 1325 (Fed. Cir. 2003)	passim
In re Lee, 277 F 3d 1338 (Fed. Cir. 2002)	59



DOCKET

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.

