IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER
PHARMACEUTICALS INC., RB
PHARMACEUTICALS LIMITED, and
MONOSOL RX, LLC,

Plaintiffs,

V.

C.A. No. 13-1674-RGA Consolidated

WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC.,

Defendant.

REDACTED VERSION D.I. 395

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,

Plaintiffs,

C.A. No. 14-0422-RGA

V.

PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP.,

Defendants.

JOINT PROPOSED FINDINGS OF FACT



TABLE OF CONTENTS

					Page	
PLA				MENT PROPOSED FINDINGS OF FACT AND ESPONSES	1	
I.		JURISDICTION AND OWNERSHIP				
	A.	The Parties				
	B.	RBP's NDA and Suboxone® Sublingual Film				
	C.	The Asserted Patents				
	D.	The Asserted Claims				
II.	TRIA	TRIAL WITNESSES ON INFRINGEMENT				
	A.	Plaintiffs' Witnesses			8	
		1.	Mart	yn Davies, Ph.D	8	
		2.	Lon	Mathias, Ph.D	9	
		3.	Wall	ace Yau, Ph.D	10	
		4.	Nadi	ne Paiement	11	
	B.	Defe	Defendants' Witnesses			
		1.	Jason	n McConville, Ph.D	11	
		2.	Kina	m Park, Ph.D	13	
		3.	Boze	ena Michniak-Kohn, Ph.D	13	
		4.	Dear	Toste, Ph.D	13	
		5.	Garr	y Myers	14	
III.		WATSON'S PROPOSED ANDA PRODUCT INFRINGES CLAIMS 62, 64, 65, 69, AND 73 OF THE '514 PATENT				
	A.	Claims 62, 64, 65, 69, and 73 of the '514 Patent				
	B. Watson Concedes That Its Proposed ANDA Product Meets All I Elements of the Asserted Claims					
			a)	Watson's proposed ANDA product is a drug delivery composition	18	
			b)	Watson's proposed ANDA Product comprises one or more substantially water swellable or water soluble polymers (polyethylene oxide and hypromellose)	18	
			c)	Watson's proposed ANDA product contains a desired amount of at least one active (buprenorphine HCl and naloxone HCl)	18	
			d)	Watson's proposed ANDA product comprises a particulate active (buprenorphine HCl) substantially uniformly stationed in the matrix	18	



TABLE OF CONTENTS (cont'd)

Page

		e)	Watson's proposed ANDA product comprises a flavor (lime flavor), and sweeteners (acesulfame potassium and maltitol)	18	
		f)	The particulate active in Watson's proposed ANDA product (buprenorphine HCl) has a particle size of 200 microns or less	19	
		g)	The matrix in Watson's proposed ANDA product is capable of being dried without loss of substantial uniformity in the stationing of the buprenorphine particulate active, as the individual unit doses of the final product do not vary by more than 10% of the desired amount of buprenorphine HCl	19	
		h)	Subsequent to casting and drying of the matrix, substantially equally sized individual unit doses do not vary by more than 10% of said desired amount of said at least one active	19	
		i)	The particulate active in Watson's proposed ANDA product (buprenorphine HCl) has a particle size of 100 microns or less, as required by dependent Claim 64	19	
		j)	The variation in the drug content of Watson's proposed ANDA product is less than 5 percent by weight per film dosage unit, as required by dependent Claim 65	19	
		k)	Watson's proposed ANDA product contains the opiate active buprenorphine HCl, as required by dependent Claim 73	19	
C.	Watson's Proposed ANDA Product Meets the Remaining Elements of the Asserted Claims				
	1.		n's proposed ANDA Product contains a "taste-masking	20	
	2.	The taste-masking agents are present in the amount of about 0.1–30% by weight of the drug delivery composition, as required by dependent Claim 69			
	3.	Watson's proposed ANDA product is "a cast film comprising a flowable water-soluble or water swellable film-forming matrix"			
	4.	The m suffici	atrix in Watson's proposed ANDA product "has a viscosity ent to aid in substantially maintaining non-self-aggregating mity of the active in the matrix"		
D.			posed ANDA Product Infringes Dependent Claims 64, 65,	36	



TABLE OF CONTENTS (cont'd)

					Page	
V.	PAR'S PROPOSED ANDA PRODUCT INFRINGES CLAIMS 62, 64, 65, 69, AND 73 OF THE '514 PATENT					
	A.	Par Does Not Dispute That Its Proposed ANDA Product Meets All But Two Elements of the Asserted Claims				
		1.		loes not dispute that its proposed ANDA product meets ents related to the active ingredients and particle size	41	
		2.		loes not dispute its proposed ANDA product meets the taste-	43	
		3.		loes not dispute its proposed ANDA product meets the ormity elements	45	
	B.	Par's Proposed ANDA Product is "a cast film comprising a flowable water-soluble or water swellable film-forming matrix"				
	C.	aid ir	The matrix in Par's proposed ANDA product "has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix"			
	D.	Par's	Par's ANDA Product Infringes Dependent Claims 64, 65, 69, and 73			
•		WATSON'S PROPOSED ANDA PRODUCT INFRINGES CLAIMS 1, 3, 6, AND 15–19 OF THE '832 PATENT				
	A.	Clair	n 1 of tl	he '832 Patent	63	
		1.	The local pH limitation		65	
			a)	Local pH may be measured in vitro	70	
			b)	Watson's ANDA specifies a pH of 3.0 to 5.0	79	
			c)	Watson's "film pH" measurements rely on a volume greater than that in the mouth	81	
		2.	The s	sufficient to optimize limitation	87	
			a)	Watson's higher dosage strengths (12 mg/3 mg & 8 mg/2 mg)	89	
			b)	Watson's lower dosage strengths (4 mg/1 mg & 2 mg/0.5 mg)	94	
	B.	Claim 3 of the '832 Patent			97	
	C.	Clair	aim 6 of the '832 Patent			
	D.	Claim 15 of the '832 Patent			99	
		1.	Wats	son's higher dosage strengths (12 mg/3 mg & 8 mg/2 mg)	100	
		2.	Wats	son's lower dosage strengths (4 mg/1 mg & 2 mg/0.5 mg)	104	
	E.	Clair	n 16-19	of the '832 Patent	107	



TABLE OF CONTENTS (cont'd)

					Page	
VI.		PAR'S PROPOSED ANDA PRODUCT INFRINGES CLAIMS 1, 3, 6, AND 15–19 OF THE '832 PATENT				
	A.	Claim 1 of the '832 Patent				
		1.				
		2.	Par's Proposed ANDA Product Meets the Local pH Limitation			
			a)	Par's ANDA lists a target pH of 3.5 to 4.0 in simulated saliva		
			b)	Par's pH measurements rely on a volume greater than that in the mouth	121	
			c)	Par's proposed ANDA product gave a measured pH of 3.5 in saliva	123	
			d)	Dr. Toste's calculations fail to include the alkaline earth metal component	124	
		3.	The	sufficient to optimize limitation	127	
			a)	Par's higher dosage strengths (12 mg/3 mg & 8 mg/2 mg)	128	
			b)	Par's lower dosage strengths (4 mg/1 mg & 2 mg/0.5 mg)	129	
	B.	Claim 3 of the '832 Patent				
	C.	Claim 6 of the '832 Patent				
	D.	Clain	aim 15 of the '832 Patent			
		1.	Par's	s higher dosage strengths (12 mg/3 mg & 8 mg/2 mg)	133	
		2.	Par's	s lower dosage strengths (4 mg/1 mg & 2 mg/0.5 mg)	133	
	E.	Clain	Claims 16–19 of the '832 Patent			
VII.	WATSON'S ANDA PRODUCT INFRINGES CLAIMS 1 AND 4 OF THE '150 PATENT					
	A.	Claims 1 and 4 of the '150 Patent			139	
	B.	Watson Concedes That Its Proposed ANDA Product Meets All But One Element of the Asserted Claims			140	
	C.	Watson's Proposed ANDA Product Meets the Remaining Element of the Asserted Claims				
	D.	PEO Used in Watson's Proposed ANDA Product			145	
	E.	PEO MW Determination			148	
	F.	GPC	GPC Analysis of Polyox N80			
	G.	PEO Blends Have a Unimodal MW Distribution				
	Н	Partitioning GPC Data			155	



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.

