UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC, Petitioner

V.

ABRAXIS BIOSCIENCE, LLC, Patent Owner

Case IPR2017-01100 Patent 8,853,260 B2

DECLARATION OF CORY J. BERKLAND, Ph.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

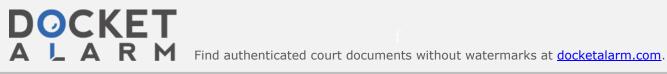


TABLE OF CONTENTS

				Page		
I.	INT	TRODUCTION1				
II.	BAG	CKGR	OUND AND QUALIFICATIONS	2		
III.	LEGAL STANDARDS USED IN MY ANALYSIS					
	A.	Prior art				
	B.	Pers	on of ordinary skill in the art	6		
	C.	Obv	iousness	7		
IV.	THE '260 PATENT					
	A.	The alleged invention				
	B.	Challenged claims				
	C.	C. Claim construction		17		
		1.	"wherein the pharmaceutical formulation is stable for at least 3 days under at least one of room temperature or refrigerated conditions"	17		
		2.	"wherein the solid core is substantially free of polymeric material"; "wherein a portion of the paclitaxel is contained within the albumin coating and a portion of the paclitaxel is associated with the free albumin"	18		
		3.	"wherein a portion of the paclitaxel is contained within the albumin coating and a portion of the paclitaxel is associated with the free albumin"	19		
V.	THE PRIOR ART					
	A.	Desai (EX1003)				
	B.	Shively (EX1004)				
	C.	Liversidge (EX1005)				



	D.	Remi	ngton'	s (EX1006)	29		
VI.	OBVIOUSNESS						
	A.	Claim 1 of the '260 patent would have been obvious					
		1. A skilled artisan would have prepared Desai's albumin-paclitaxel shells as 200-nm nanoparticles					
		2.		lled artisan would have suspended the albumin- taxel nanoparticles at a concentration of 5 mg/ml	39		
		3.		lled artisan would have reasonably expected the nin-paclitaxel nanoparticles to remain stable.	42		
			a.	A skilled artisan would expect no substantial precipitation—an inherent result of small nanoparticles.	43		
			b.	A skilled artisan would expect no substantial change in particle size—an inherent result of albumin	51		
	B.	Claims 2–3 would have been obvious.					
	C.	Claims 4 and 18–22 would have been obvious6					
	D.	Claims 5–6 would have been obvious.					
	E.	Claims 7–9 would have been obvious.					
	F.	Claims 10–11 would have been obvious					
	G.	Claims 12–14 and 16–17 would have been obvious					
	H.	Claim 15 would have been obvious.					
	I.	Claims 23–27 would have been obvious.					
	J.	J. There are no relevant secondary considerations indicati the challenged claims would not have been obvious					
		1.		allegedly "unexpected" stability of albumin-paclitaxel particles was not compared to the closest prior art	79		



	2.	The allegedly "unexpected" stability of smaller particles		
		and narrower size distributions would have been expected	81	
VII.	CONCLUS	ION	84	



EXHIBITS CITED

Exhibit	Description
1001	Desai et al., U.S. Patent No. 8,853,260 B2, "Formulations of Pharmacological Agents, Methods for the Preparation thereof and Methods for the Use thereof" (issued Oct. 7, 2014) (the "'260 patent")
1003	Desai et al., U.S. Patent No. 5,439,686, "Methods for <i>In Vivo</i> Delivery of Substantially Water Insoluble Pharmacologically Active Agents and Compositions Useful therefor" (issued Aug. 8, 1995) ("Desai")
1004	Shively, U.S. Patent No. 5,407,683, "Pharmaceutical Solutions and Emulsions Containing Taxol" (issued Apr. 18, 1995) ("Shively")
1005	Liversidge et al., U.S. Patent No. 5,399,363, "Surface Modified Anticancer Nanoparticles" (issued Mar. 21, 1995) ("Liversidge")
1006	Remington's Pharmaceutical Sciences (18th ed. 1990), Chapt. 19, "Disperse Systems," and Chapt. 78, "Sterilization" ("Remington's")
1009	FDA Guideline on Sterile Drug Products Produced by Aseptic Processing (June 1987, reprinted June 1991 and Feb. 1997)
1010	EMEA Guidance on Manufacture of the Finished Dosage Form (April 1996)
1011	Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc., Judgment and Verdict Form, No. 06-438-GMS, Dkt. 614 (D. Del. June 16, 2008)
1021	U.S. Application No. 11/520,479, Declaration of Neil P. Desai Pursuant to 37 C.F.R. § 1.132 (dated Jan. 27, 2012) ("First Inventor Declaration")
1024	U.S. Application No. 11/520,479, Supplemental Declaration of Neil P. Desai Pursuant to 37 C.F.R. § 1.132 (dated Nov. 1, 2013) ("Second Inventor Declaration")
1026	U.S. Pharmacopoeia 23 (1995 ed.) (excerpted)
1027	List et al., U.S. Patent No. 5,389,382, "Hydrosols of Pharmacologically Active Agents and their Pharmaceutical Compositions Comprising Them" (issued Feb. 14, 1995) ("List")



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