UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

AMNEAL PHARMACEUTICALS LLC
Petitioner

V.

HOSPIRA, INC Patent Owner

Inter Partes Review No. IPR2016-01579 Patent 8,455,527

DECLARATION OF ALPASLAN YAMAN, PH.D.

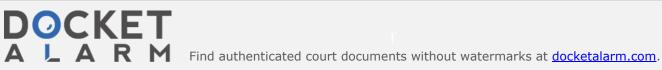


TABLE OF CONTENTS

I.	INTRODUCTION						
II.	QUALIFICATIONS & BACKGROUND						
III.	INFORMATION CONSIDERED						
IV.	THE '527 PATENT						
	A.	Background of the Technology					
		i.	History of Dexmedetomidine	7			
		ii.	Formulation of Parenteral Drugs	8			
		iii.	"Ready to Use" Formulations	12			
	B.	Scop	pe of the '527 Patent	13			
V.	CLAIM CONSTRUCTION						
	A.	A. A Person of Ordinary Skill in the Art (POSA)13					
	B.	Broadest Reasonable Interpretation14					
	C.	Claim Terms of the '527 Patent					
		i.	"Ready To Use"	15			
		ii.	"Dexmedetomidine"	17			
VI.	PRIOR-ART REFERENCES DISCLOSE ALL OF THE ELEMENTS						
	OF THE CLAIMS OF THE '527 PATENT						
	A.	A. A Person of Ordinary Skill in the Art Would Have Been					
	Motivated to Perform the Invention of Claims 1-11 and 13 of the '527						
	Pate	Patent by the 2010 Precedex Label in View of Palmgren					
		i.	Claim 1	20			



		ii.	Claims 2-5	27		
		iii.	Claims 6-11 and 13	28		
	B.	Grou	nd 2: A Person of Ordinary Skill in the Art Would Have			
	Been Motivated to Make the Invention of Claims 1-11 and 13 of the					
	'527 Patent by U.S. 6,716,867 in view of the 2010 Precedex Label and					
	Palm	gren		32		
	C.	Grou	nd 3: A Person of Ordinary Skill in the Art Would Have			
	Been	Motiv	rated to Make the Invention of Claims 1-11 and 13 of the			
	'527 Patent by the 2010 Precedex Label in View of Giorgi, Eichhorn,					
	Palm	gren, a	and the Lavoisier Documents	38		
VII.	COI	NCLU	DING STATEMENTS	43		



I. INTRODUCTION

- I, Alpaslan Yaman, Ph.D., declare as follows:
- 1. I am over 18 years of age. I have personal knowledge of the facts stated in this declaration and could testify competently to them if asked to do so.
- 2. In this proceeding before the U.S. Patent and Trademark Office ("USPTO"), I have been retained by Amneal Pharmaceuticals LLC ("Amneal" or "Petitioner") as an independent expert consultant. Although I am receiving compensation at my standard consulting rate for the time that I spend on this proceeding, I have no other interest in its result. I also expect to be reimbursed for reasonable expenses incurred in relation to my consulting. My compensation is independent of the opinions rendered or the outcome of this proceeding.
- 3. I understand that this proceeding involves U.S. Patent No. 8,455,527 ("the '527 patent"), Ex. 1001, issued on June 4, 2013, and that the '527 patent issued from U.S. Patent Application Serial No. 13/678,148 ("the '148 application"), Ex. 1054, filed on November 15, 2012. The '148 application is a continuation of U.S. Application No. 13/541,524, Ex. 1048, now U.S. Patent No. 8,338,470 ("the '470 patent"), Ex. 1053, which is a continuation of U.S. Application No. 13/343,672, Ex. 1008, now U.S. Patent No. 8,242,158 ("the '158 patent"), Ex. 1047, which was filed on January 4, 2012. Accordingly, the earliest possible effective filing date of the '527 patent is January 4, 2012.



- 4. I have been asked by counsel for Amneal to explain the technical subject matter of the '527 patent and its background. I have also been asked to explain whether prior art discloses the methods claimed in the '527 patent. My opinions are set forth below.
- 5. Generally, the '527 patent disclosure and claims are directed to premixed pharmaceutical compositions of dexmedetomidine and methods of use of the premixed compositions for sedation. Ex. 1001, col. 2, ll. 3-9, col. 10, ll. 1-25. The specification provides suitable containers including glass vials, ampoules, syringes, and plastic flexible containers, such as polyvinyl chloride (PVC), VisIVTM, polypropylene, and CR3 containers. *Id.* at col. 9, ll. 21-29. The specification also provides numerous suitable concentrations for the premixed concentrations, including the claimed concentration range of between about 0.005 to about 50 μg/mL. *Id.* at col. 7, l. 44 col. 8, l. 19.
- 6. It is my opinion that a person of ordinary skill in the art ("POSA") would have had a reason and the know-how to arrive at the subject matter recited in claims 1-11 and 13 by combining the disclosure of the 2010 Precedex label, Ex. 1007, in view of the Palmgren reference, Ex. 1017, with a reasonable expectation of success.
- 7. Also, it is my opinion that a person of ordinary skill in the art would have had a reason and the know-how to arrive at the subject matter recited in



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.

