IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CORPAK MEDSYSTEMS, INC. and HALYARD HEALTH, INC., Petitioners

ν.

KIRN MEDICAL DESIGN, L.L.C. and APPLIED MEDICAL TECHNOLOGY, INC.,

Patent Owner

U.S. Patent No. 6,631,715 to Kirn

Inter Partes Review No.: IPR2017-01990

Petition for *Inter Partes* Review of U.S. Patent No. 6,631,715 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42

DECLARATION OF TERRY LAYTON, PH.D

## TABLE OF CONTENTS

I.	OVERVIEW OF MY ENGAGEMENT 1					
II.	QUALIFICIATIONS AND PROFESSIONAL BACKGROUND 2					
III.	LEG. A.			ARDS		
IV.	BAS A. B. C. D. E.	Mate State Perso The ' GRO	2. Simmons			
				For Simmons Element 18a: A method of placing and securing at least one tube through a nose into a patient	.27	
			ii) iii)	comprising Element 18b: Inserting the at least one tube into a first or second nare of the nose Element 18c: Inserting an end portion of a flexible		
			iv)	member having a magnet attached thereto into a first nare of the nose Element 18d: Inserting a magnetic probe into a second nare of the nose for attracting said magnet and said end portion of said flexible member		
			v)	Element 18e: Removing said probe from the second nare of the nose thereby retrieving said end portion of said flexible member through the second nare of the nose		
			vi)	Element 18f: And snapping the at least one tube into a channel formed in a receiver		
	F.		ENT C	2: OBVIOUSNESS OF CLAIM 18 OF THE '715 OVER BALLANTYNE IN VIEW OF IZUMI i	.40	

		i. Claim 18 Would Have been Obvious Over Ballantyne in View of Izumi	43
	G.	GROUND 3: OBVIOUSNESS OF CLAIM 18 OF THE '715	
		PATENT OVER BALLANTYNE IN VIEW OF BIERMAN	
		AND SIMMONS	
		1. Bierman	53
		i. Claim 18 Would Have been Obvious Over Ballantyne in	
		View of Bierman and Simmons	55
V.	SEC	ONDARY CONSIDERATIONS	67
VI.	CON	CLUSION	67

### **EXHIBITS**

EXHIBIT 1001	U.S. Patent No. 6,631,715
EXHIBIT 1002	U.S. Patent No. 5,185,005 ("Ballantyne")
EXHIBIT 1003	"A New Nasal Bridle for Securing Nasoentereal Feeding Tubes" by Jeffrey A. Meer
EXHIBIT 1004	Declaration of Dr. Terry Layton
EXHIBIT 1005	"Securing of intermediate duration feeding tubes" by W. Frederick McGuirt
EXHIBIT 1006	"The Bridle: Increasing the Use of Nasoenteric Feedings" by Albert Barrocas
EXHIBIT 1007	U.S. Patent No. 5,752,511 ("Simmons")
EXHIBIT 1008	U.S. Patent No. 5,097,827 ("Izumi")
EXHIBIT 1009	Patent Owner's Initial Infringement Contentions
EXHIBIT 1010	"Feeding Tube Anchor" by Albert Levenson
EXHIBIT 1011	PCT International Application Publication No. WO 99/20334 ("Bierman")
EXHIBIT 1013	IPR2017-00646, Paper 9 (Decision) (P.T.A.B. July 26, 2017)
EXHIBIT 1015	IPR2017-00646, Paper 7 (Preliminary Response) (P.T.A.B. April 28, 2017)

I, Terry N. Layton, Ph.D., do hereby declare and say as follows:

I have been asked to provide testimony as to what one of ordinary skill in the art would have understood with respect to the patent at issue and various prior art reference(s). I provide this testimony below.

#### I. OVERVIEW OF MY ENGAGEMENT

Counsel for Petitioners has requested that I provide declaratory
evidence, in the form of analysis and opinions, in the above-captioned *Inter Partes* Review proceeding ("IPR"). I understand that this IPR involves U.S. Patent No.
6,631,715. I refer to this patent as either the "715 patent" or as "EX1001" in this declaration.

2. For this IPR, I have been asked to provide analysis and expert opinions on whether Claim 18 of the '715 patent, under the claim construction standards that apply during *Inter Partes* Review proceedings, is invalid under 35 U.S.C. § 103 as having been obvious over specific references in the prior art from the standpoint of one of ordinary skill in the art ("POSA") as defined below as of the relevant priority date.<sup>1</sup>

3. Further, I have personal knowledge of the facts contained in this Declaration, am of legal age, and am otherwise competent to testify.

4. For my work as an expert in the IPR engagement, I am being

<sup>&</sup>lt;sup>1</sup> The relevant priority date is discussed below.

# DOCKET A L A R M



# 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.