# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mako Surgical Corp.
Petitioner

V.

Blue Belt Technologies, Inc.
Patent Owner

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CASE NO: IPR2015-00630 PATENT NO: 6,205,411

**DECLARATION OF DR. KEVIN CLEARY** 

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Blue Belt Technologies, Inc. Exhibit 2003 Mako Surgical Corp. v. Blue Belt Technologies, Inc. IPR2015-00630



## TABLE OF CONTENTS

INTR	ODUCTION AND QUALIFICATIONS	3
LEVI	EL OF ORDINARY SKILL IN THE ART	6
APPI	LICABLE LEGAL STANDARD	9
A.	Claim Construction	9
B.	Obviousness	9
The '	976 Patent	10
THE		
CITE	D REFERENCES	23
A.	DiGioia	23
B.	DiGioia II	24
C.	Taylor	26
D.	Chao	27
E.	O'Toole	27
Obviousness of claims 1–15 and 17 over DiGioia		28
A.	"the pre-operative kinematic biomechanical simulator outputs a	
	in independent claims 1 and 10.	28
B.	"wherein said pre-operative geometric planner outputs at least	
	5 ,	33
C		55
<b>C</b> .	•	35
Propo	-	
	PROPLEVI APPI A. B. The 'THE CITE A. B. C. D. E. Obvid A. B.	B. Obviousness. The '976 Patent. THE '411 PATENT. CITED REFERENCES A. DiGioia B. DiGioia II C. Taylor D. Chao E. O'Toole. Obviousness of claims 1–15 and 17 over DiGioia A. "the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component," as recited in independent claims 1 and 10.  B. "wherein said pre-operative geometric planner outputs at least one geometric model of the joint," as recited in independent claims 1 and 10.



#### I. INTRODUCTION AND QUALIFICATIONS

- 1. I have been retained on behalf of Blue Belt Technologies, Inc., to provide this Declaration concerning technical subject matter relevant to the *inter* partes review of U.S. Patent No. 6,205,411 ("the '411 Patent") (Ex. 1001).
- **2.** 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.

### II. PROFESSIONAL QUALIFICATIONS

- 3. My name is Kevin Robert Cleary. I currently reside at 8416 Buckhannon Drive, Potomac, MD 20854. I hold a Doctor of Philosophy degree in Mechanical Engineering from the University of Texas, and Bachelor of Science and Master of Science degrees in Mechanical Engineering and Materials Science from Pratt School of Engineering at Duke University. I was a postdoctoral researcher in robotics at the Mechanical Engineering Laboratory in Tsukuba, Japan in 1990.
- 4. I have more than 15 years of experience as an engineer, research investigator, and professor in the image-guided surgery industry. I am currently the Technical Director of the Bioengineering Initiative at the Sheikh Zayed Center for Pediatric Surgical Innovation at the Children's National Medical Center in Washington, D.C. and a Professor at the School of Health Sciences at George Washington University. My past experiences include experience as a Research



Professor and Director at the Imaging Science and Information Systems (ISIS)

Center in the Georgetown University Radiology Department.

- I have played numerous roles in advancing the field of image-guided 5. surgery and medical robotics. I have been actively involved in the field of robotics since at least 1986 and in the field of medical imaging since at least 1996. From January 1994 to December 1996 I served as a Robotics System Engineer and Group Leader at Global Associates Ltd., Inc. in Arlington, VA, where I started a program to demonstrate the usefulness of robots to Federal Agencies. January 1996 to January 2000, I served as a Research Assistant Professor at the Imaging Science and Information Systems Center in the Department of Radiology of Georgetown University. As a Research Assistant Professor, I developed "teleradiology" systems that allow for remote imaging of a patient using, for example, computed tomography (CT) scan data. During this time, I also developed imageguided medical intervention technologies that helped guide medical procedures using medical image data.
- 6. I was the principal organizer of a 2004 conference titled "Operating Room of the Future" with topics including image-guided surgery and medical robotics. I led the world's first clinical trial of robotically assisted spine blocks at Georgetown University. My research was funded by the National Institute of Health (NIH) through the R01 grant mechanism to develop an open-source



software toolkit for image-guided surgery. (The R01 grant mechanism provides support for health-related research and development.) This toolkit was used by more than 20 research groups worldwide. I led the team that did the world's first image-guided liver biopsy at Georgetown University using electromagnetic tracking. This work was recently extended to PET-CT guided biopsy. I have written review articles on image-guided surgery and medical robotics. I was the co-editor of popular book in the field titled "Image-Guided Interventions." At Children's National Medical Center I am currently managing projects in image-guided surgery, medical robotics, and biomedical devices.

- 7. Attached hereto as Appendix A is a true and correct copy of my most recent CV describing my education, employment history, publications, professional activities and awards, and patents.
- **8.** In light of the foregoing, I consider myself to be an expert in the fields of image-guided medical devices and surgical robotics, and believe that I am qualified to provide an opinion as to what a person of ordinary skill in the art would have understood, known, or concluded regarding the subject matter of the '411 Patent at the time of its earliest priority date, which I understand to be in or around February 1997.



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