

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent of: Frederick E. Shelton, IV
U.S. Pat. No.: 8,479,969 Attorney Docket No.: 11030-0049IPA
Issue Date: July 9, 2013
Appl. Serial No.: 13/369,609
Filing Date: Feb. 9, 2012
Title: DRIVE INTERFACE FOR OPERABLY COUPLING A
MANIPULATABLE SURGICAL TOOL TO A ROBOT

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**DECLARATION OF DR. BRYAN KNODEL
IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 8,479,969
(GIORDANO AS PRIMARY REFERENCE)**

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 B. Claims 1-11 and 24 are invalid as obvious over Giordano in view
 of Wallace and further in view of Tierney102

 C. Claims 1-6 and 9-10 are invalid as obvious over Shelton in view of
 Wallace and Tierney103

 D. Claims 7, 8, 11, and 24 are invalid as obvious over Shelton in view
 of Giordano and further in view of Wallace and Tierney103

 E. Claims 5 and 6 are invalid as obvious over Giordano in view of
 Wallace and Tierney, and further in view of Hueil104

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I, Bryan Knodel, declare as follows:

1. I have been engaged as an expert by Fish & Richardson P.C. on behalf of Intuitive Surgical, Inc. (“Petitioner”) for the above-captioned *inter partes* review. I understand that this proceeding involves United States Patent No. 8,479,969 entitled “Drive Interface for Operably Coupling a Manipulatable Surgical Tool to a Robot” by Frederick E. Shelton IV, filed February 9, 2012 and issued July 9, 2013 (the “’969 Patent” or “’969”). I understand that the ’969 Patent is currently assigned to Ethicon LLC.

2. I have reviewed and am familiar with the specification of the ’969 Patent. I will cite to the specification using the following format (’969 Patent, 1:1-10). This example citation points to the ’969 Patent specification at column 1, lines 1-10.

3. I have reviewed and am familiar with the file history of the ’969 Patent (“FH”). I understand that the file history is being provided as an exhibit in a single PDF document. I will cite to the PDF pages when I cite to the file history.

4. I have also reviewed the Petition for *Inter Partes* Review of the ’969 Patent and am familiar with the following prior art used in the Petition:

- IS1014 U.S. Patent App. No. 2008/0167672 to Giordano et al. (“Giordano”)
- IS1008 U.S. Patent No. 6,699,235 to Wallace *et al.* (“Wallace”)

- IS1009 U.S. Patent No. 6,331,181 to Tierney et al. (“Tierney”)
- IS1015 U.S. Patent No. 6,978,921 to Shelton et al. (“Shelton”)
- IS1016 U.S. Patent App. No. 2007/0158385 to Hueil et al. (“Hueil”)

5. I have been asked to provide my technical review, analysis, insights and opinions regarding the '969 Patent and the above-noted references.

I. QUALIFICATIONS

6. My resume is being provided with this Declaration. As indicated there, I have eight publications and I am a named inventor on over 130 patents for medical devices. I have extensive experience with surgical instruments, and surgical staplers in particular, which is the subject matter of the '969 Patent.

7. Specifically, I have been involved in the research and development, design, and manufacture of medical devices including surgical cutting and stapling devices since 1992, and am qualified to present the analysis provided in this declaration.

8. I was employed in the Research and Development department as an engineer of Ethicon Endo-Surgery. I was the lead design engineer for endoscopic linear staplers/cutters. In this lead design engineer role, it was my responsibility to understand every aspect of these devices.

9. One early patent of mine is U.S. Patent No. 5,465,895, entitled “Surgical Stapler Instruments,” and granted on November 14, 1995. This patent is referenced in the Background section of the '969 Patent's specification as

“disclos[ing] an endocutter with distinct closing and firing actions,” but was not cited by the Examiner during prosecution. ’969 Patent, 2:13-16. The ’895 Patent states: “The present invention relates in general to surgical stapler instruments which are capable of applying lines of staples to tissue while cutting the tissue between those staple lines and, more particularly, to improvements relating to stapler instruments and improvements in processes for forming various components of such stapler instruments.” My ’895 Patent specifically discloses jaws that open and close and a gear-driven knife to cut stapled tissue. I am thus generally familiar with such mechanisms for surgical instruments.

10. Beginning in 1998, I have been a consultant for medical device companies and law firms. I have consulted in the areas of conceptual design, prototyping, and turnkey product design.

11. In addition, I have worked on a variety of surgical products for use in a wide range of surgical procedures including female reproductive system, female incontinence, female pelvic floor dysfunction, lung volume reduction, colon, GERD, bariatrics, CABG, heart valve repair, hernia, general surgical procedures, and surgical stapling, which is the general subject matter of the patent-at-issue.

12. As part of my consulting practice, I have also acted as a non-testifying expert in a patent litigation case in the area of medical devices.

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