

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Christopher J. Schall, et al.
U.S. Patent No.: 7,490,749 Attorney Docket No.: 11030-0052IP1
Issue Date: February 17, 2009
Appl. Serial No.: 11/729,355
Filing Date: March 28, 2007
Title: SURGICAL STAPLING AND CUTTING INSTRUMENT WITH
MANUALLY RETRACTABLE FIRING MEMBER

DECLARATION OF BRYAN KNODEL

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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. 7,490,749

entitled “Surgical Stapling and Cutting Instrument With Manually Retractable Firing Member” attributed to inventors Christopher J. Schall and Chad P.

Boudreaux, filed March 28, 2007 and issued February 17, 2009 (the ’749 Patent). I

understand that the ’749 is currently assigned to Ethicon LLC.

2. I have reviewed and am familiar with the specification of the ’749 Patent. I will cite to the specification using the following format (’749 Patent, 1:1-

10). This example citation points to the ’749 Patent specification at column 1,

lines 1-10. I also have reviewed and am familiar with the file history of the ’749 Patent IS1002).

3. I have also reviewed the Petition for *inter partes* Review of the ’749 Patent and am familiar with the following prior art used in the Petition:

- IS1004 U.S. Patent Publication No. 2006/0175375 to Shelton et al. (“Shelton II”)
- IS1005 U.S. Patent Publication No. 2005/0178813 to Swayze et al. (“Swayze”)
- IS1006 U.S. Patent No. 8,322,455 to Shelton et al. (“Shelton I”)

4. I have also reviewed the documents listed below, which I refer to throughout this Declaration.

- IS1008 How Design Teams Use DFM/A to Lower Costs and Speed Products to Market (1996) (retrieved from http://www.ame.org/sites/default/files/target_articles/96q1a2.pdf)
- IS1009 Electronic Comparison of Written Description of Swayze (US 2005/0178813; Original) to Shelton II (US 2006/0175375; Underline/Strikethrough)
- IS1010 U.S. Patent No. 5,941,442
- IS1011 U.S. Patent No. 5,865,361
- IS1012 Excerpts from McGraw-Hill Dictionary of Scientific and Technical Terms (6th Edition, 2003)

5. I have been asked to provide my technical review, analysis, insights and opinions regarding the '749 Patent and the above-noted references.

I. QUALIFICATIONS

6. My *curriculum vitae* 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 '749 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 ’749 Patent’s specification as “an example of a surgical stapler . . . which advantageously provides distinct closing and firing actions.” ’749 Patent, 2:13-16. My ’895 Patent states (at 1:1-10):

“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.”

Similar to the ’749 Patent, the surgical instrument described in my ’895 Patent includes a pistol-grip handle assembly supporting a stapling and severing end effector at the distal end of an elongate shaft assembly, with manually operated firing and closure triggers. I am thus quite familiar with such mechanisms for surgical instruments.

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