

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner.

IPR2018-01247
U.S. Patent No. 8,479,969

DECLARATION OF DR. ELLIOTT FEGELMAN

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	QUALIFICATIONS AND BACKGROUND.....	1
III.	OVERVIEW OF OPEN, TRADITIONAL LAPAROSCOPIC, AND ROBOTIC LAPAROSCOPIC SURGICAL PROCEDURES	3
IV.	PASSIVE ARTICULATION WITH ROBOTIC SURGICAL TOOLS WOULD NOT HAVE BEEN CLINICALLY ACCEPTABLE TO SURGEONS IN THE 2011 TIMEFRAME	9
V.	JURAT	11

I. INTRODUCTION

1. My name is Dr. Elliott Fegelman. I have been asked by counsel for Patent Owner Ethicon LLC (“Patent Owner”) to offer my opinions from the perspective of a practicing surgeon in connection with the above-captioned proceeding. I understand from counsel that the 2011 timeframe is the relevant timeframe for this proceeding, and I was a practicing general surgeon at that time.

2. Unless otherwise stated, the statements in this declaration are based on my personal knowledge, my experience as a surgeon and hospital administrator for nearly 30 years, and the documents cited in this declaration. I am currently employed by and being compensated by Ethicon Endo-Surgery, Inc. (an affiliate of Patent Owner), but I am not being separately compensated for my time in preparing this declaration. If called as a witness, I could and would attest to the statements in this declaration under oath.

II. QUALIFICATIONS AND BACKGROUND

3. I received a Doctor of Medicine degree from Wright State University in 1988. I then completed my residency in general surgery at the University of Cincinnati College of Medicine in 1994. After completing my residency, I joined the faculty at the University of Cincinnati as an assistant professor. I continued to be a professor at the University of Cincinnati until 2009.

4. Starting in 1994, I also was employed at the Christ Hospital in Cincinnati as a general surgeon. I ultimately achieved the position of Chief of Surgery at the Christ Hospital in 2000. I retained that role until July 2002, when I accepted the role of Chief of Surgery at the Jewish Hospital in Cincinnati, Ohio. I retained that position until August 2011.

5. Between 1998 and 2012, while in private practice, I consulted for Ethicon Endo-Surgery, Inc. for approximately four hours per week on a variety of surgical matters. In September 2012, I retired from active surgical practice and accepted a full-time role at Ethicon Endo-Surgery, Inc. From 2012 to 2015, I was a medical director in the area of metabolic disease. Starting in 2015, I moved out of that area and now focus on evaluating third-party technologies across the general surgery platform.

6. During my career as a general surgeon, I have performed numerous open and laparoscopic procedures. During these procedures, I worked extensively with open surgical instruments and hand-held laparoscopic surgical instruments. Examples of laparoscopic surgical instruments that I have used during my career include but are not limited to graspers (forceps), scissors, needle drivers, energy devices, clip applicators, and endocutters.

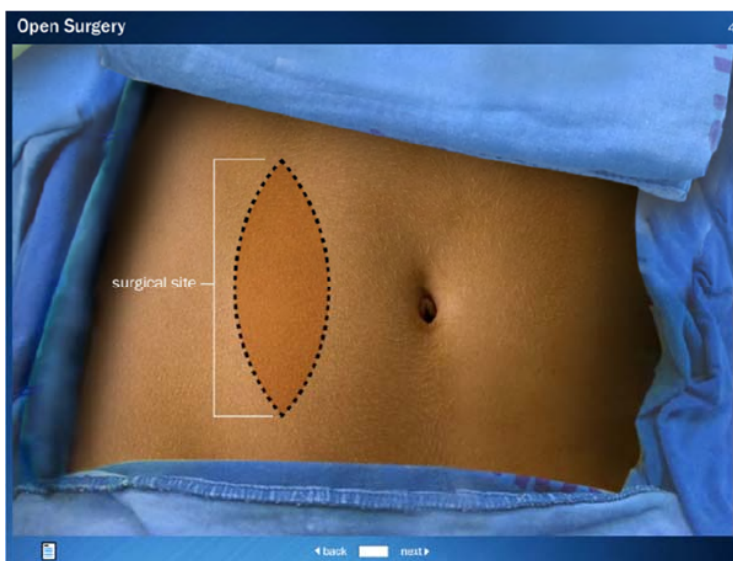
7. During my career, I also became experienced with robotic surgery systems offered by Intuitive Surgical, Inc. and performed numerous surgeries using

the da Vinci Si surgical system. Examples of robotic laparoscopic surgical instruments that I have used during my career include but are not limited to graspers (forceps), scissors, needle drivers, energy devices, and clip appliers. At the time of my retirement, a robotic endocutter was not available.

III. OVERVIEW OF OPEN, TRADITIONAL LAPAROSCOPIC, AND ROBOTIC LAPAROSCOPIC SURGICAL PROCEDURES

8. I will start with a general overview of relevant aspects of open, traditional laparoscopic,¹ and robotic laparoscopic surgical procedures.

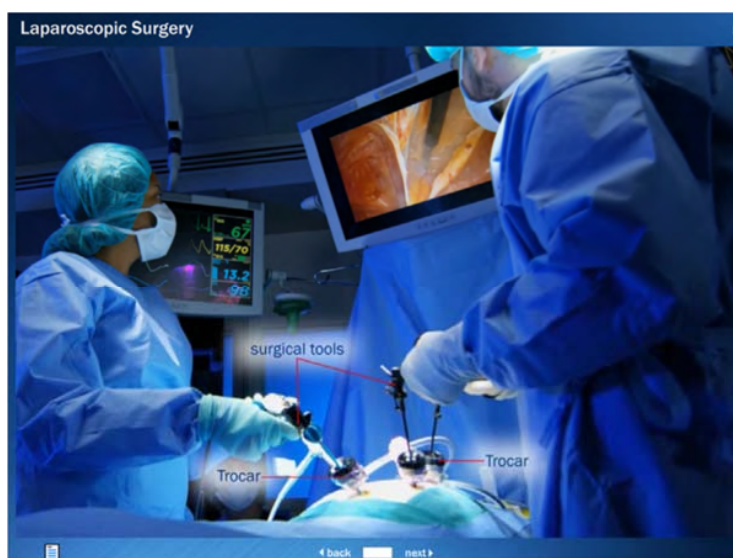
9. In an open procedure, a large incision gives the surgeon direct access to the surgical site. This is illustrated below:



Ex. 2001.006 (Excerpts from Ethicon's Technology Tutorial)

¹ By "traditional," I am referring to laparoscopic procedures that do not involve robotic systems.

10. In contrast, traditional laparoscopic and robotic laparoscopic (i.e., “minimally invasive”)² procedures involve several smaller incisions. Devices called trocars (or cannulas)² are inserted through the incisions, which provide a pathway to the surgical site. Hand-held or robotic laparoscopic surgical tools are then inserted through this pathway. A traditional laparoscopic procedure using hand-held laparoscopic surgical tools is illustrated below. In the illustration, hand-held laparoscopic surgical tools have been inserted through trocars and the surgeon is viewing the surgical site on video:



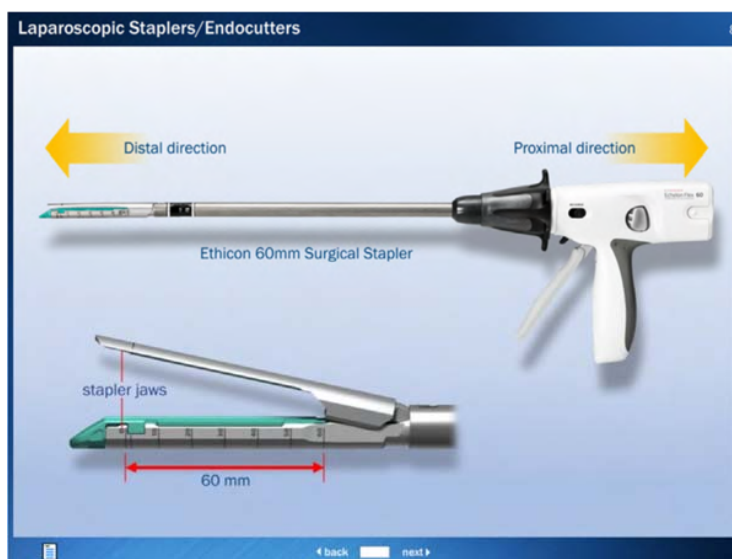
Ex. 2001.007 (Excerpts from Ethicon’s Technology Tutorial)

² I will use the term trocars in this declaration to refer to both trocars and cannulas, which I consider interchangeable.

11. Because the incisions are small in laparoscopic procedures, laparoscopic surgical tools typically have a narrow shaft that fits through the trocar pathway. The portion of the instrument that engages tissue (i.e., the end effector) is at the end of the shaft that reaches the surgical site.

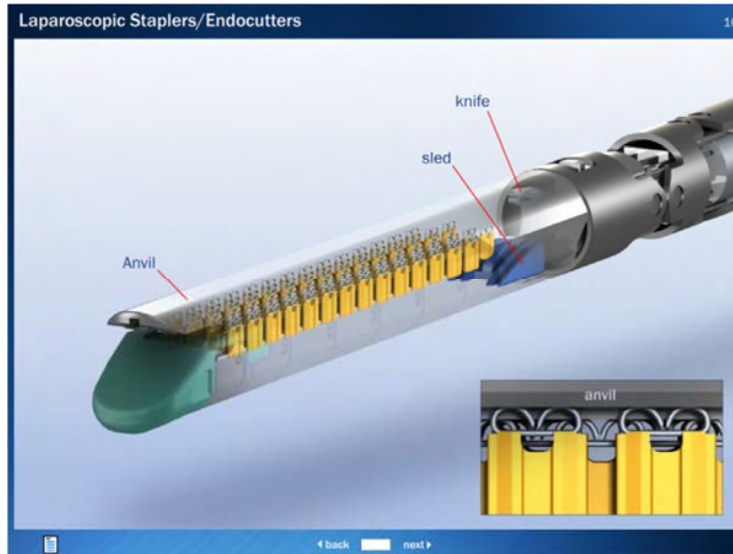
12. The narrow trocar pathway restricts movement of the shaft of laparoscopic surgical tools. However, it may be necessary to approach tissue from multiple different angles. Thus, it may be desirable to move the end effector with respect to the shaft to change the angle of the end effector with respect to the tissue. This is also called articulation.

13. I will elaborate on the operation of endocutter tools to provide an example of articulation. Endocutters are laparoscopic surgical tools that include an end effector with stapler jaws. An Ethicon hand-held endocutter is shown below:



Ex. 2001.010 (Excerpts from Ethicon's Technology Tutorial)

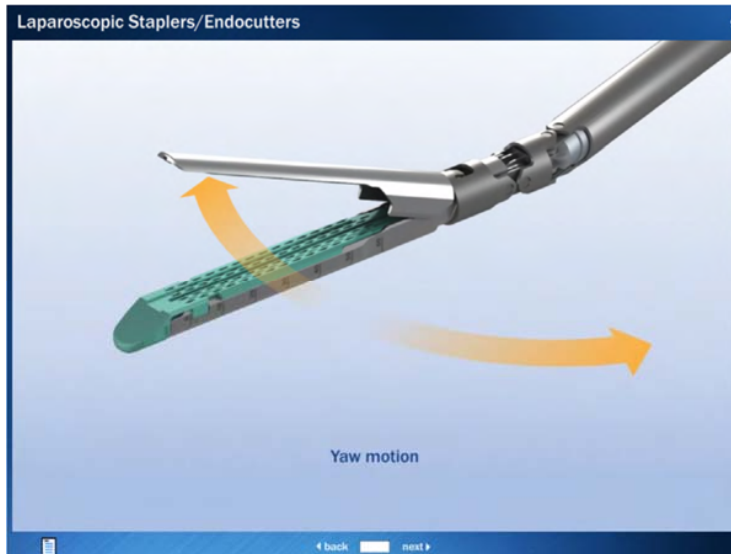
14. When an endocutter is fired, a sled translates through the endocutter's end effector and drives staples upwards through clamped tissue on opposite sides of a knife that trails the sled and cuts the tissue. This is illustrated below:



Ex. 2001.012 (Excerpts from Ethicon's Technology Tutorial)

15. Endocutters are used in a variety of procedures, including, for example, thoracic, bariatric, and colorectal surgeries. These surgeries involve cutting and stapling tissue.

16. An example of articulating an endocutter end effector from side-to-side (also called yaw motion) is illustrated below:



Ex. 2001.011 (Excerpts from Ethicon's Technology Tutorial)

17. Articulation may be passive or active. Surgical tools that include passive articulation require external forces to articulate. In other words, passive articulation requires pressing the exterior of the end effector against another surgical instrument or structure in the body to articulate the end effector. The surgeon then locks the end effector in place.

18. Active articulation refers to devices that allow the surgeon to control articulation without external forces. For example, actively articulated hand-held laparoscopic surgical tools typically include knobs, buttons, levers, etc. that the surgeon can operate to articulate the end effector.

19. Because passive articulation brings the end effector into contact with other structures, passive articulation requires nearly instantaneous, tactile feedback to ensure that excessive forces are not applied to the structures. This is particularly

true when the exterior of the end effector is being pressed against a structure in the body. With hand-held laparoscopic devices, the surgeon's grip on the hand-held portion (which is connected to the end effector through the shaft of the instrument) provides this tactile feedback. The surgeon also views the surgical site on video; however, the video does not provide an indication of the forces that are being applied. Thus, the tactile feedback provided through the surgeon's grip on the hand-held portion is critical to the use of passive articulation.

20. In contrast to hand-held laparoscopic surgical tools, robotic laparoscopic surgical tools are mounted onto an instrument arm of the robotic system. The surgeon operates the tools remotely from a surgeon console and does not directly interface with them. This is illustrated below:



Ex. 2008.001 (Excerpts from Ethicon's Technology Tutorial)

21. Based on my experience using robotic surgical platforms, to the extent robotic tools could articulate, they were actively articulated by the surgeon at the console. I am not aware of any passively articulated robotic surgical tools at the time of my retirement in 2012 nor am I aware of any that exist today.

IV. PASSIVE ARTICULATION WITH ROBOTIC SURGICAL TOOLS WOULD NOT HAVE BEEN CLINICALLY ACCEPTABLE TO SURGEONS IN THE 2011 TIMEFRAME

22. As noted above, passive articulation requires pressing the exterior of the end effector against another structure to articulate the end effector. Performing passive articulation requires real-time, tactile feedback—and the ability to adapt to that feedback quickly—to prevent damage to both the surgical tool itself as well as the structure that is providing the articulation force. In hand-held devices, the surgeon has real-time, tactile feedback because the surgeon is holding the device and feels it press against another structure. The surgeon also has the ability to make nearly instantaneous decisions based on the tactile feedback.

23. In the 2011 timeframe, robotic systems did not provide a surgeon with any type of tactile feedback relating to forces applied to the exterior of the end effector. Moreover, robotic laparoscopic surgical systems available at this time did not provide haptic feedback relating to forces applied by gripping tools when gripping tissue. *See also, e.g.,* Ex. 2009 at 523, Mucksavage et al., *Differences in Grip Forces Among Various Robotic Instruments and da Vinci Surgical Platforms*,

Journal Of Endourology, Vol. 25, No. 3 (March 2011) (“Due to the lack of haptic feedback, visual cues are necessary to estimate grip forces and tissue tensions during surgery.”); *id.* at 526 (“The current robotic platforms do not employ the use of haptic feedback.”); *id.* at 527 (“Although the current technology may be limited by the lack of direct haptic feedback, this study is the first to establish direct forces exerted by the robotic instruments.”).

24. Some sort of haptic or other tactile feedback would be necessary in order to perform passive articulation with a robotic tool safely and effectively. Although video of the surgical site is available, this would not be an acceptable substitute for tactile feedback for the same reasons that video feedback is not an acceptable substitute during a traditional laparoscopic procedure. In particular, a robotic surgeon would have found video feedback alone to be unacceptable when performing passive articulation because the video does not provide an indication of the forces being applied.

25. Further, from a surgeon’s perspective in the 2011 timeframe, one of the key perceived benefits of a robotic tool was the ability to have complete control over the movement of the tool from the surgeon console. Passive articulation relinquishes this control and instead requires external forces to control the movement of the tool. As a result, passive articulation would negate this key perceived benefit of robotic surgery tools.

26. Thus, based on my surgical experience and the discussion above, it is my opinion that a surgeon would have found a robotic tool with passive articulation to be clinically unacceptable in the 2011 timeframe.

V. JURAT

27. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

28. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on April 19, 2019



Dr. Elliott Fegelman