IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent of:	Shelton, IV	
U.S. Pat. No.:	8,479,969	Attorney Docket No.: 11030-0049IP5
Issue Date:	July 9, 2013	11030-0049IPA
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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SUPPLEMENTAL DECLARATION OF DR. BRYAN KNODEL IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,479,969 IPR2018-01247 IPR2018-01254

I, Bryan Knodel, declare as follows:

I. INTRODUCTION

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 previously submitted a declaration in this matter that provides my qualifications, and this declaration responds to specific issues raised in the Patent Owner Response and supporting expert declarations in this proceeding.

II. RESPONSE TO SPECIFIC ISSUES RAISED BY PATENT OWNER

3. I understand that Patent Owner has submitted declarations by Dr. Fegelman (a surgeon) and Dr. Awtar in support if the Patent Owner Response. In those declarations, both Dr. Fegelman and Dr. Awtar assert that handheld linear stapler/cutters would not be combined with Anderson or Wallace (which disclose surgical robots) because those surgical robots allegedly fail to disclose tactile feedback, and that a handheld linear stapler/cutter with passive articulation, such as disclosed by

Timm would not be combined Anderson, as I proposed because, again, Anderson does not disclose tactile feedback.

4. I disagree with those conclusions for two reasons. First, a person of ordinary skill in the art would have understood that both Anderson and Wallace in fact disclose tactile feedback. Second, even if they had not disclosed tactile feedback, a person of ordinary skill in the art would nonetheless have been motivated to make the combinations I propose (including Timm with Anderson and Giordano/Shelton with Wallace).

5. As the ’969 Patent explains, there are different forms of feedback in robotic systems, which can include video feedback and tactile feedback. Video feedback allows a surgeon operating a surgical robot to see what the end effectors are doing so that the surgeon can properly control the movement of the end effectors. Tactile feedback is force feedback to the surgeon’s hands so that the surgeon feels the forces being applied to the end effectors. The ’969 Patent explains: “the robotic controller 1001 system may provide the surgeon with an indication that signifies the closure of the anvil. Such indication may be, for example, in the form of a light and/or audible sound, tactile feedback on the control members, etc.” ’969 Patent, 67:32-36.

6. With regard to passive articulation, Dr. Fegelman has stated:

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.
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> Fegelman Declaration, ¶19.

7. While I agree that passive articulation against **a structure in the body** raises concerns of damaging tissue due to excessive force, such concerns may be addressed by a skilled surgeon, and in any event are not applicable when passive articulation is performed by pressing one instrument against another instrument. Tactile feedback is not a necessity and is not "critical" when using passive articulation against a second instrument.

8. Accordingly, passive articulation is not a necessity and is not critical in the proposed combination of Timm with a surgical robot because Timm expressly discloses passive articulation either by pressing against a body organ or

by pressing against another instrument. Accordingly, a person of ordinary skill in the art reading Timm would be motivated to combine Timm with a surgical robot and employ Timm's passive articulation with the expectation that the passive articulation would be performed, as taught by Timm, at least by pressing the instrument against another instrument. Timm specifically discloses:

> To use this embodiment, the clinician positions the tool assembly 100 in the patient and then **applies an articulation force to the tool assembly with another surgical instrument** or by bringing the tool assembly 100 into contact with a portion of the patient to articulate the tool assembly to a desired position before drawing the actuation member 3050 in the proximal direction PD.

Timm, 32:32-38.

9. The above passage from Timm is quoted by Dr. Awtar (at paragraph 41 of his Declaration). However, nothing in Timm mandates that the second option (pressing against the body) for use of passive articulation must be used, and a person of ordinary skill in the art would readily understand that either option may be used. A person of ordinary skill in the art would understand that when adapting Timm to a robot that lacked tactile feedback, a surgeon could simply articulate one instrument by pressing it against another instrument. Tactile feedback is not necessary or critical when using passive articulation in this manner. Furthermore,

the surgeon remains in complete control of the process because a surgeon would typically operate multiple instruments with the surgical robot.

10. To the extent that Dr. Awtar intended to assert that tactile feedback for passive articulation against **another instrument** is necessary or critical, such an assertion is unsubstantiated.

11. Moreover, there is nothing in Timm that defines the force required to actuate the passive articulation joint. A person of ordinary skill in the art would be well capable of designing the passive articulation joint that moves easily in its unlocked state with minimal resistance such that the actuation force would be minimal. Thus the articulation force could be designed to be low enough to easily permit articulation against another instrument, or even against an internal anatomical structure. In fact, there are internal anatomical structure options that are quite robust and many that are delicate. A skilled surgeon could easily choose an appropriate structure to safely articulate the instrument using a low force passive articulation mechanism.

12. It must be remembered that robotic surgical instruments, such as graspers, are used against body tissue without tactile feedback and there is no basis to conclude that passive articulation would require more forces than those applied by other instruments against the body. I note that although Dr. Awtar discusses the forces provided by such instruments (e.g., at paragraph 81), he does not explain

why those instruments are in fact able to be used without the alleged "critical" tactile feedback, but for some reason passive articulation forces would require tactile feedback.

13. Moreover, the entire discussion about the lack of tactile feedback is not relevant here because both Anderson and Wallace disclose robotic systems that have tactile feedback.

14. Anderson states:

> The control System typically includes at least one processor which relays input commands from the master control devices to the associated robotic arm and instrument assemblies and from the arm and instrument assemblies to the associated master control devices in the case of, e.g., force feedback, or the like.
>
> Anderson, 2:62-3:1.

15. A person of ordinary skill in the art would understand that this passage refers to tactile feedback in which forces from the manipulation of the instruments are fed back to the master control devices, which are the controllers held by the surgeon. (Anderson, 16:14-24 (discussing the master controllers) and 6:33-37 (discussing feedback sensors in the motor pack, which can detect forces on the instrument by the resistance the motor senses as it tries to move the instrument or hold the instrument in a single position).

16. Wallace likewise discloses tactile feedback. Wallace is largely focused on a wrist mechanism and thus leaves much of the discussion of the surgical robot to incorporated material. Wallace incorporates by reference other references for the disclosure of the surgical robot in general. One such incorporated reference is U.S. Patent Application No. 08/975,617:

> Robotic surgery systems and methods are further described in co-pending U.S. patent application Ser. No. 08/975,617, filed Nov. 21, 1997, the full disclosure of which is incorporated herein by reference.

Wallace, 3:25-29.

17. This application issued as U.S. Patent No. 6,132,368. That incorporated reference states: "Position, force, and tactile feedback sensors (not shown) may also be employed to transmit position, force, and tactile sensations from the surgical tools back to the surgeon's hands as he/she operates the telerobotic system." Accordingly, a person of ordinary skill in the art would understand that Wallace discloses a robotic system with tactile feedback. U.S. Patent No. 6,132,368, 3:43-48; 5:9-18; 5:46-67; 9:56-66.

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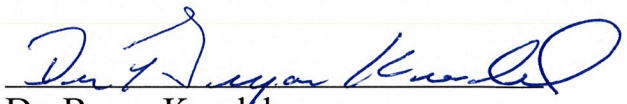
III. CONCLUSION

I hereby 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. I further declare that these statements are 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).

Executed this 15th day of July, 2019.



Dr. Bryan Knodel