UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION,

Petitioner

v.

KARL STORZ ENDOSCOPY-AMERICA, INC.,

Patent Owner

Patent No. 8,439,821

Issue Date: May 14, 2013

Title: SYSTEM AND METHOD FOR THE CENTRAL CONTROL OF DEVICES USED DURING AN OPERATION

IPR Number 2015-00679

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

Exhibit 1001: U.S. Patent No. 8,439,821

Exhibit 1002: File History Of U.S. Patent No. 8,439,821

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Exhibit 1004: U.S. Patent No. 6,278,975 ("Brant")

Exhibit 1005: U.S. Patent No. 5,781,442 ("Engleson")

Exhibit 1006: Service of Complaint in *Karl Storz Endoscopy-America, Inc. v. Stryker Corp. and Stryker Communications, Inc.*, Case No. 14-00876 (N.D. Cal.)

Exhibit 1007: Declaration of Harold J. Walbrink

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Stryker Corporation ("Stryker" or "Petitioner") respectfully petitions for *inter partes* review ("IPR") of claims 1-11 of U.S. Patent No. 8,439,821 ("the '821 patent"), which issued on May 14, 2013, and is assigned to Karl Storz Endoscopy-America, Inc. ("KSEA" or "Patent Owner").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner Stryker Corporation is the real party-in-interest. Stryker Communications, Inc., a wholly owned subsidiary of Stryker Corporation, is also an interested party.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

KSEA asserted the '821 patent against Stryker in *Karl Storz Endoscopy-America, Inc. v. Stryker Corp. & Stryker Communications, Inc.*, Case No. 14-00876 (N.D. Cal.), filed February 26, 2014 ("the litigation"). KSEA served the complaint on Stryker no earlier than March 4, 2014. (Ex. 1006.) U.S. Patent App. No. 13/864,014, which is currently pending, claims priority to the '821 patent's application. Stryker is filing petitions for *inter partes* review of the other four patents that KSEA asserted against Stryker in the litigation. (*See* IPR Nos. 2015-00672, 2015-00673, 2015-00674, 2015-00675, 2015-00677, 2015-00678, 2015-00764.)

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel. Pursuant to 37 C.F.R. § 42.8(b)(4), a Power of Attorney accompanies this Petition. Lead Counsel: Robert A. Surrette (Reg. No. 52,262), bsurrette@mcandrews-ip.com. Back-up Counsel: Merle S. Elliott (Reg. No. 52,857), melliott@mcandrews-ip.com; Christopher M. Scharff (Reg. No. 53,556), cscharff@mcandrews-ip.com; and Caroline A. Teichner (Reg. No. 71,689), cteichner@mcandrews-ip.com. Post and Delivery: McAndrews, Held & Malloy, 500 West Madison St., 34th Floor, Chicago, IL 60661. Telephone: 312-775-8000. Facsimile: 312-775-8100.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided in Section I.C of this Petition. Petitioner also consents to electronic service by email at: StrykerKSIPR@mcandrews-ip.com.

II. PAYMENT OF FEES – 37 C.F.R. § 41.103

The required fee has been paid online. Please charge any fee deficiencies or credit any overpayments to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R § 42.104

A. Grounds For Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '821 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR of the '821 patent.

B. Identification Of Challenge Under 37 C.F.R. § 42.104(b) And Relief Requested

Petitioner requests *inter partes* review of claims 1-11 of the '821 patent on the grounds set forth below and requests that these claims be found unpatentable. An explanation of how claims 1-11 are unpatentable under specified statutory grounds is provided below, including an identification of where each element is found in the prior art and the relevance of each reference. Additional explanation and support for this IPR and each ground of rejection is set forth in the Declaration of Harold J. Walbrink (Ex. 1007), which is submitted in accordance with 37 C.F.R. § 1.68. *Inter partes* review of claims 1-11 is requested in view of the following references:[1]

- U.S. Patent No. 6,928,490 ("Bucholz"), issued on Aug. 9, 2005, filed on May 19, 2000, and claims priority to a provisional application filed on May 20, 1999, which is §102(e) prior art (Ex. 1003);
- U.S. Patent No. 6,278,975 ("Brant"), issued on Aug. 21, 2001, filed on Aug. 19, 1999, and claims priority to a parent application filed on Aug. 30, 1996 and a provisional of that parent filed on Oct. 25, 1995, which is §102(e) prior art (Ex. 1004); and
- U.S. Patent No. 5,781,442 ("Engleson") issued July 14, 1998, which is §102(b)

[1] The earliest claimed priority date for the 821 patent is September 5, 2000.

prior art (Ex. 1005).

Ground	Proposed Statutory Rejections for the '821 patent
1	Claims 1-10 anticipated by Bucholz
2	Claims 1-10 obvious in view of Bucholz and the knowledge of a person of ordinary skill in the art
3	Claims 8, 11 obvious in view of Bucholz in combination with Brant
4	Claims 3, 9 obvious in view of Bucholz in combination with Engleson

C. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review is given its "broadest reasonable construction in light of the specification of the patent in which it appears," which may be a broader construction than applied by courts during claim construction. 37 C.F.R. § 42.100(b); *see also Corning Optical Comm. RF, LLC v. PPC Broadband, Inc.*, IPR2013-00340, Paper 79 (P.T.A.B. Nov. 21, 2014); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Further, "[c]onsistent with the broadest reasonable construction, claim terms are presumed to have their ordinary and customary meaning, as understood by a person of ordinary skill in the art, in the context of the entire patent disclosure." *AOL Inc. v. COHO Licensing, LLC*, IPR2014-771, Paper 10 (P.T.A.B. Nov. 20, 2014).

Petitioner proposes the following claim constructions:[2]

In independent claims 1 and 10, the term "***medical device having safety-related functions***" means "a device whose breakdown or failure during a medical procedure may be life-threatening for a patient." (Ex. 1007, Walbrink Decl. at ¶ 30.) This construction comports with the special meaning given to this term by the patentee. (*See id.*; Ex. 1001, '821 patent at 1:54:62; *see also id.* at Abstract, 1:66-2:40, 3:18-31, 3:46-48, 4:15-20, 5:22-33, 5:66-6:4.) Accordingly, the term a "***device having non-safety-related functions***," as used in claims 1 and 10, means "a device whose breakdown or failure would not be life-threatening for a patient." (Ex. 1007, Walbrink Decl. at ¶ 30.)

Also in independent claims 1 and 10, the term "***wherein said second controller can only control devices that do not have safety-related functions***" means that "the second controller can issue control commands only to devices that do not have safety-related functions and cannot issue control commands to devices that have safety-related functions." (*Id.* at ¶ 31.) The claims are consistent with this construction. Claim 1 of the '821 patent recites that "said second controller can only control devices that do not have safety-related functions." (Ex. 1001, '821 patent at claim 1.) Similarly, claim 10 of the '821 patent recites that "said

[2] Because of the different claim construction standard in litigation, Petitioner reserves all of its rights with regard to constructions during litigation.

second controller can only control devices that do not have safety related functions." (*Id.* at claim 10.) By reciting that the second controller can only control devices that do not have safety-related functions, the claims of the '821 patent necessarily require that the second controller cannot control devices that do have safety-related functions. (Ex. 1007, Walbrink Decl. at ¶ 32.)

Claim 1 of the '821 patent also recites "a touch panel that communicates a control command associated with said at least one medical device having safety-related functions and a control command associated with said at least one device having non-safety related functions to said second controller." (*Id.* at claim 1 (emphasis added); *see also id.* at claim 10.) Claim 1 further requires that "said second controller controls said at least one device having non-safety-related functions based on the control command associated therewith received from said touch panel" and "said second controller communicates the control command associated with said at least one medical device having safety related functions received from said touch panel to said first controller." (*Id.* (emphasis added).) Because claim 1 requires that the second controller controls other devices based on control commands, claim 1 supports that the second controller controls other devices by issuing control commands to them. The language of the claims thus supports Stryker's proposed construction. (Ex. 1007, Walbrink Decl. at ¶ 32.)

The prosecution history of U.S. Patent Application No. 12/364,328, which

issued as the '821 patent, also supports this construction. In particular, the prosecution history shows that the second controller can issue control commands only to devices having non-safety-related functions. During prosecution, the applicant explained as follows: "If the command is associated with a non-safety related device, then the command is issued by the second controller. If the command is associated with a safety device, then the second controller simply passes the command on to the first controller." (Ex. 1002, File History of '821 patent at 187-88; *see also id.* at 158-60.) This excerpt from the prosecution history supports Stryker's construction that control commands for safety-related devices are not issued by the second controller. (*See also* Ex. 1001, '821 patent at Abstract, 1:66-2:40, 2:41-50, 3:1-7, 3:18-31, 3:56-67, 4:15-20, 4:43-45, 4:50-59, 5:22-33, 6:5-14, 6:16-19; Ex. 1007, Walbrink Decl. at ¶ 34.)

IV. BACKGROUND OF THE '821 PATENT

The '821 patent, which was filed on February 2, 2009 and claims an earliest priority date of September 5, 2000, is directed toward a system and method for controlling medical devices. (Ex. 1001, '821 patent at Abstract, Claims, 1:18-22.) The '821 patent has 11 claims. Claims 1 and 10 are independent claims.

In claim 1**,** the '821 patent purports to claim "[a] system for controlling medical devices, comprising a first controller; at least one medical device having safety-related functions controlled by said first controller; a second controller in

communication with said first controller; at least one device having non-safety-related functions controlled by said second controller; a touch panel that communicates a control command associated with said at least one medical device having safety-related functions and a control command associated with said at least one device having non-safety related functions to said second controller; wherein said second controller controls said at least one device having non-safety-related functions based on the control command associated therewith received from said touch panel; and wherein said second controller communicates the control command associated with said at least one medical device having safety related functions received from said touch panel to said first controller." (*Id.* at claim 1.) Claim 10 recites a "method for controlling medical devices" with steps that correspond to the limitations of independent claim 1. (*Id.* at claim 10.) All dependent claims are directed to known types of safety-related and non-safety-related devices, as well as known functionality of the first and second controllers.

Medical device control systems like that disclosed in the '821 patent are nothing new. (Ex. 1007, Walbrink Decl. at ¶¶ 43-55.) Microprocessors were first introduced to the medical industry in the early 1980s. (*See id.* at ¶ 44.) Prior to the advent of microprocessors, medical control systems had been designed with hardware dedicated to specific functions within the device. (*See id.* at ¶ 45.) In other words, particular operations of medical devices were hard-wired in circuitry,

rather than being programmed into software. (*See id.*) If a function needed to be modified or upgraded, the entire circuit had to be redesigned. (*See id.*) Microprocessors allowed the functions and performance of medical devices to be modified without redesign of the circuity because the functionality is programmable. (*See id.*) Thus, microprocessors greatly improved the flexibility of medical control systems, provided an easier means for resolution of performance issues, and allowed for functionality to be added to the system, which prolonged the life of the product line. (*See id.*)

With the advent of microprocessors and software, the need arose to ensure that the software was being executed as intended. (*See id.* at ¶ 46.) The programmability of software brought with it the potential for missing a step, or executing a routine out of order, which could result in system malfunction. (*See id.*) For instance, if the software used to control a surgical device failed to execute properly, it could result in surgical error and patient injury. (*See id.*) To overcome this risk of software malfunction, medical device engineers began to make use of safety mechanisms, such as the use of "watchdog" timers in medical control systems. (*See id.*)

A "watchdog" timer is typically a separate processor or other dedicated hardware that is used to ensure the safety-critical functioning of the system. (*See id.* at ¶ 47.) On a regular basis, such as every 20 milliseconds, the watchdog timer

will be reset by the main processor. (*See id.*) If the microprocessor experiences a glitch and begins to operate outside of its programmed routine, it will fail to reset the watchdog timer. (*See id.*) If the watchdog timer is not reset, it will time out. (*See id.*) This causes a "priority interrupt," which is a command to the microprocessor to execute a safe shutdown routine. (*See id.*) This watchdog function therefore ensures that the system is executing its programmed function safely and as designed. (*See id.*) If the system stops executing its programmed function safely, it will be shut down as safely as possible. (*See id.*) The watchdog is generally independent from the system software so that it will not be affected by software bugs or errors in the software. (*See id.*)

As microprocessors became more prevalent, single-board computers that ran off-the-shelf operating systems became available. (*See id.* at ¶ 48.) Designers of medical device control systems began to use these computers in control systems. (*See id.*) The operating system software was designed for commercial use in personal computers, not created for the unique purposes of a medical device control system. (*See id.*) Accordingly, the operating system software often performed many non-essential functions that could interfere with the safety-related functions of the medical control system. (*See id.*) To overcome this problem, software developers began to create versions of operating system software that were more stable for medical control applications. (*See id.*) This software could

be verified and validated, which means that the software was rigorously tested to make sure that it operated as intended, even under adverse operating conditions and hardware errors. (*See id.*)

It was also common at this time for medical device developers to separate non-essential, ancillary functions from safety-related functions. (*See id.* at ¶ 49.) This was typically accomplished using separate processors or controllers. (*See id.*) One controller would be used for safety-related functions, and the other controller would be used for non-safety-related functions. (*See id.*)

Therefore, the idea of separating out the control of safety-related and non-safety related processes in medical device control systems is not new. (*See id.* at ¶ 52.) Designers of medical device control systems routinely treat safety-related and non-safety-related processes differently, and have done so since well before the alleged invention of the '821 patent. (*See id.*)

In other words, the distinction between safety-related and non-safety-related functions is routinely considered as a matter of course by persons of ordinary skill in designing medical control systems. (*See id.* at ¶ 53.) It would have been obvious to a person of ordinary skill at the time of the alleged invention of the '821 patent to treat safety-related information and safety-related systems on a priority basis. (*See id.*) That prioritization could be achieved either with software or with hardware, such as by using a separate controller for safety-related devices, as

disclosed in the '821 patent. (*See id.*)

Prior art systems also recognized the advantages of shielding medical controllers from outside interference. (*See id.* at ¶ 54.) For example, U.S. Patent No. 6,928,490 ("Bucholz") discloses "[a] network infrastructure for an operating room, comprising a plurality of medical devices, each device of which is connected through a single communication channel to the network, wherein each device may be controlled through a local interface, or through a remote interface available through the network." (Ex. 1003, Bucholz at Abstract.) Bucholz discloses that "the network infrastructure . . . controls devices within the operating room, while ensuring that operating devices are not accidentally controlled from outside the operating room unless specifically granted authorization by the local surgeon." (*Id.* at 4:18-23 (emphasis added).) Bucholz further explains that "extraneous Internet network traffic is selectively prevented from entering the operating room's network through controller 100. Thus, the surgeon can exercise control of devices within the operating room with a relatively fast response time and secure patient information, while gaining access to Internet 210. . . . [T]he network within each operating room must be isolated from stray network traffic that could interfere with communications within a given operating theater. Such isolation is offered by the current invention." (*Id.* at 6:2-7 (emphasis added), 4:45-48.)

Like the '821 patent, Bucholz therefore discloses preventing non-safety-

related Internet data from interfering with the control of medical devices being used within the operating room. (Ex. 1007, Walbrink Decl. at ¶ 55.) Bucholz, like the '821 patent, speaks to the benefits of a "'closed system,'" which "does not allow any intervention from outside the system. Such a system cannot be manipulated, reconfigured etc. neither by a user directly nor via the internet etc." (Ex. 1001, '821 patent at 2:23-30 (emphasis added).) Bucholz recognizes that such isolation increases the overall safety of the medical device control system. (Ex. 1003, Bucholz at 4:45-49; Ex. 1007, Walbrink Decl. at ¶ 55.)

V. ELEMENT-BY-ELEMENT ANALYSIS OF HOW CHALLENGED CLAIMS ARE UNPATENTABLE (37 C.F.R. §§42.104)

There is a reasonable likelihood that claims 1-11 are unpatentable as anticipated or rendered obvious in view of the prior art.

A. Ground 1: Claims 1-10 Are Anticipated Under 35 U.S.C. § 102(e) By Bucholz

Claims 1-10 are anticipated under 35 U.S.C. § 102(e) by Bucholz. Bucholz is missing only the microphone element of claim 11, which, as discussed in §§ V.B-D below, would have been obvious.

(i) Independent claims 1 and 10:

Independent claims 1 and 10 feature similar elements and will be addressed together. To the extent the preamble is limiting, Bucholz discloses a "system [and method] for controlling medical devices," as recited by claims 1 and 10, respectively. (Ex. 1003, Bucholz at 1:9-13 ("[T]he present invention relates to a

simplified infrastructure for an operating room that allows control of highly complex devices and provides for communication among devices."); Ex. 1007, Walbrink Decl. at ¶¶ 59-60.)

Each element of independent claims 1 and 10 is found in Bucholz. ***First***, Bucholz discloses "***a first controller***," as recited by claim 1. Bucholz explains that "bipolar coagulator 400 includes embedded controller 410 . . . . Each device is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:16-20; *see also id.* at 6:11-51; Ex. 1007, Walbrink Decl. at ¶ 60.)

Second, Bucholz discloses "***at least one medical device having safety-related functions controlled by said first controller***," as recited by claim 1. Bucholz discloses a bipolar coagulator 400, where the "bipolar coagulator 400 includes embedded controller 410 . . . . Each device is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:16-20.) Bipolar coagulators are devices having safety-related functions because their breakdown or failure during a medical procedure may be life-threatening for a patient. (*See* § III.C above.) In particular, bipolar coagulators are used during surgical procedures to stop bleeding at the surgical site. If the bipolar coagulator were to breakdown or fail, the surgeon may be

unable to stop the patient from bleeding at the surgical site, which could result in life-threatening injury to the patient. (Ex. 1007, Walbrink Decl. at ¶ 60.)

Independent claim 10 combines the first and second elements of claim 1, the disclosure of which is discussed above, and recites: "***connecting a first controller to at least one medical device having safety-related functions***." (Ex. 1003, Bucholz at 6:16-20; *see also id.* at Figs. 1, 4, 6:11-51, 7:10-13.) By definition, embedded controller 410 is connected to the bipolar coagulator 400 by virtue of being "embedded." (*See* Ex. 1007, Walbrink Decl. at ¶ 60.)

Third, Bucholz discloses "***a second controller in communication with said first controller***," as recited by claim 1. Bucholz discloses an embedded controller 310 in a microscope 300, which is in communication with the embedded controller 410 in bipolar coagulator 400 (i.e., the "*first controller*") via a local area network, as expressly disclosed in Figure 1 below:

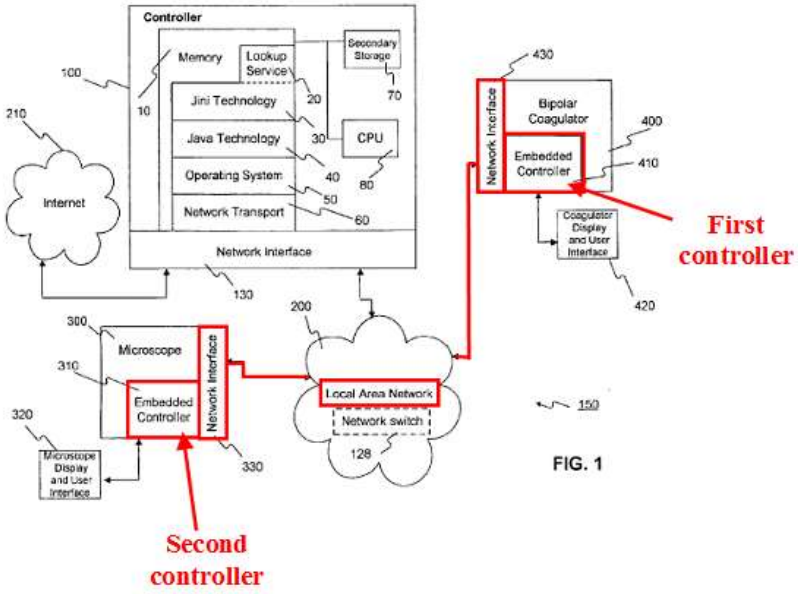
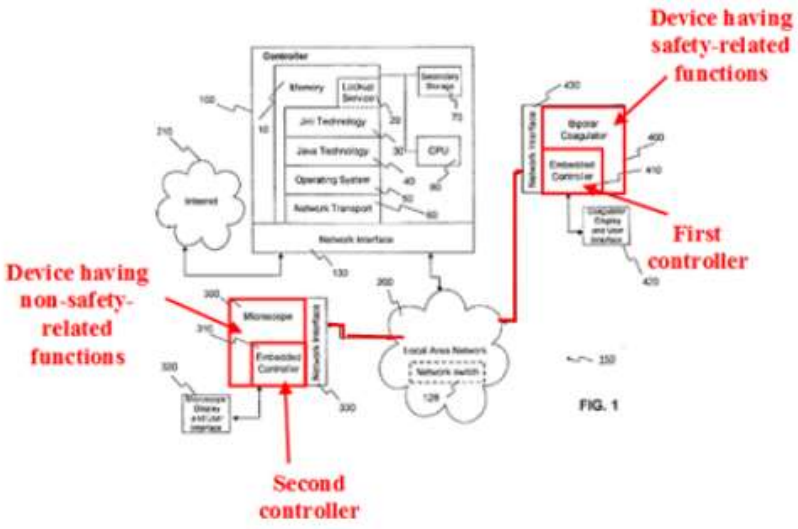


FIG. 1

(Ex. 1003, Bucholz at Fig. 1 (annotated), 6:16-20, 6:58-7:10; (Ex. 1007, Walbrink Decl. at ¶ 60.)

Fourth, Bucholz discloses "***at least one device having non-safety-related functions controlled by said second controller***," as recited by claim 1. Bucholz teaches that microscope 300 is controlled by embedded controller 310. (Ex. 1003, Bucholz at 6:17-20 ("[M]icroscope 300 includes embedded controller 310. Each device is controlled locally using its own embedded controller that drives a display and user interface device."); *see also id.* at 6:11-51, Fig. 1.) Microscopes are devices having non-safety-related functions because their breakdown or failure during a medical procedure would not be life-threatening for a patient. (*See* § III.C above.) Surgical microscopes are optical devices, although they may include a controller and related electronic components for actuating their physical position. If the electronic components of the surgical microscope were to break down or fail during a procedure, the surgeon could still look through the microscope (i.e., the optical function of the microscope would not be adversely affected). (Ex. 1007, Walbrink Decl. at ¶ 60.) Moreover, the surgeon or a nurse in the operating room could manually adjust the position of the microscope, even if the electronic position control failed. (*See id.*) Therefore, a microscope is properly considered a "*non-safety-related device.*" (*See id.*)

Independent claim 10 combines the third and fourth elements of independent claim 1, the disclosure of which is discussed above, and recites: "***connecting a second controller to at least one device having non-safety-related functions***" and "***connecting the first controller to the second controller***." (Ex. 1003, Bucholz at 6:16-20, 6:58-7:10; *see also id.* at 6:11-50, Figs. 1, 4.) By definition, embedded controller 310 is connected to the microscope 300 by virtue of being "embedded." (Ex. 1007, Walbrink Decl. at ¶ 60.) And, for the reasons described above regarding the local area network, Bucholz discloses "*connecting the first controller to the second controller*." The elements discussed above are shown in the following figure:



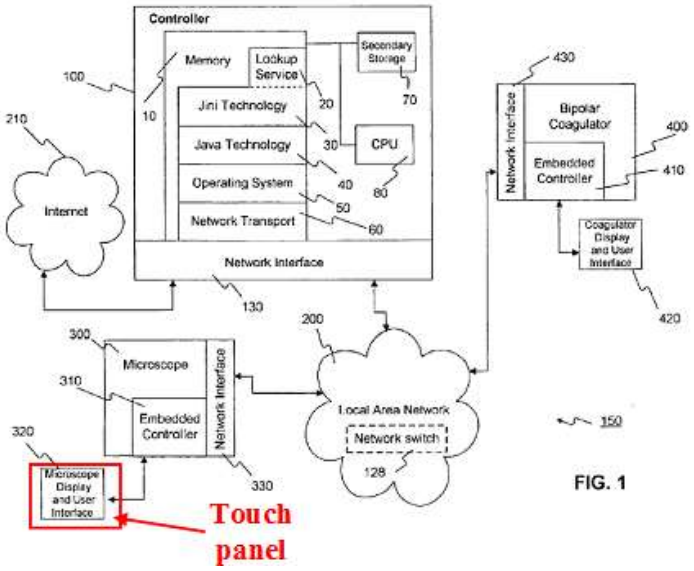
(Ex. 1003, Bucholz at Fig. 1 (annotated); Ex. 1007, Walbrink Decl. at ¶ 60.)

Fifth, Bucholz discloses that "***said second controller can only control devices that do not have safety-related functions***," as recited by claim 1. Bucholz

teaches that "[e]ach device is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:18-20 (emphasis added).) Accordingly, embedded controller 310 ("*said second controller*") can control only microscope 300 and display and user interface 320. For the reasons discussed above, microscope 300 is a non-safety-related device. Display and user interface 320 is also a non-safety-related device because, if display and user interface 320 were to break down or fail during a procedure, the user could simply use the coagulator display and user interface 420 to input control commands to the microscope 300. (*See id.* at 6:58-7:10; *see also* § V.A.ii below; Ex. 1007, Walbrink Decl. at ¶ 60.) Therefore, embedded controller 310 can only control non-safety-related devices. (Ex. 1007, Walbrink Decl. at ¶ 60.) Embedded controller 310 cannot control bipolar coagulator 400, a device having safety-related functions, because bipolar coagulator 400 is controlled locally by its own embedded controller 410. (*See id.*) Claim 1 of Bucholz also discloses this claim element. It identifies two controlled devices—namely, "a first controlled device" [bipolar coagulator] and "a second controlled device" [microscope]—where each "controlled device [is] responsive only to [its own] controller." (Ex. 1003, Bucholz at claim 1; *see also id.* at 6:11-7:17; Ex. 1007, Walbrink Decl. at ¶ 60.)

Sixth, Bucholz discloses "***a touch panel that communicates a control command associated with said at least one medical device having safety-related***

functions and a control command associated with said at least one device having non-safety related functions to said second controller," as recited by claim 1. Bucholz discloses a display and user interface 320 connected to microscope 300, as shown in Figure 1 below:



(Ex. 1003, Bucholz at Fig. 1 (annotated); *see also id.* at 5:43-47.) Bucholz recites that the display and user interfaces "include[] a touch-sensitive flat panel." (*Id.* at 6:24-26.) As shown in Fig. 2 below, Bucholz discloses that display and user interface 420 communicates control commands associated with bipolar coagulator 400 to embedded controller 410:

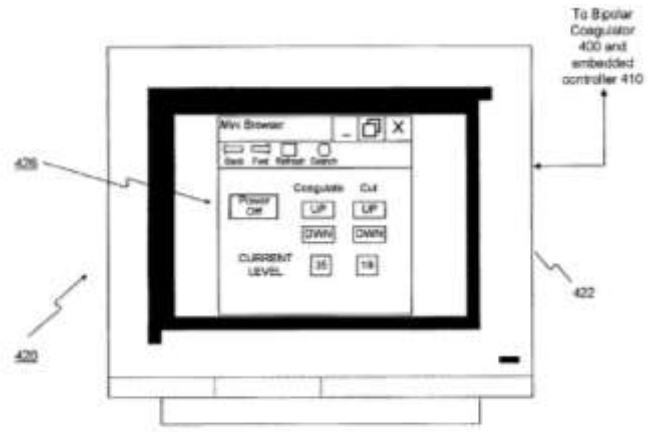


FIG. 2

(*Id.* at Fig. 2.) To the extent not expressly disclosed, Bucholz inherently teaches that display and user interface 320 (the "*touch panel*") likewise communicates control commands associated with microscope 300 ("*said at least one medical device having non-safety related functions*") to embedded controller 310 ("*said second controller*"). (*See id.* at 6:52-7:17; Ex. 1007, Walbrink Decl. at ¶ 60.)

Bucholz further discloses that display and user interface 320 can also communicate control commands associated with bipolar coagulator 400 ("*said at least one medical device having non-safety related functions*"), as follows: "By pressing the button marked 'coagulator,' the minibrowser of microscope display and user interface 320 will display the control form for bipolar coagulator 400, and all functions of bipolar coagulator 400 can be manipulated through the control form as displayed on the minibrowser of microscope display and user interface 320." (Ex. 1003, Bucholz at 6:58-7:10.) Display and user interface 320 is driven by embedded controller 310 ("*said second controller*"). (*Id.* at 6:18-20 ("Each

device is controlled locally using its own embedded controller that drives a display and user interface device.").) Thus, when commands for either the microscope or the bipolar coagulator are inputted into display and user interface 320, they are received by embedded controller 310. (Ex. 1007, Walbrink Decl. at ¶ 60.)

Seventh, Bucholz discloses that "***said second controller controls said at least one device having non-safety-related functions based on the control command associated therewith received from said touch panel***," as recited by claim 1. Bucholz teaches that "[e]ach device"—including microscope 300—is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:18-20.) Furthermore, Bucholz explains that, "[w]hen a user touches a button to request a desired task [on display and user interface 420 of bipolar coagulator 400], minibrowser 426 activates embedded controller 410 through an interface so that embedded controller 410 controls bipolar coagulator 400 to perform the desired task." (*Id.* at 6:33-37.) To the extent not expressly disclosed, Bucholz inherently teaches that embedded controller 310 functions the same way, such that embedded controller 310 ("*said second controller*") controls microscope 300 ("*said at least one device having non-safety-related functions*") based on the control command associated therewith received from display and user interface 320 ("*said touch panel*"). (*See id.*; *see also id.* at 6:11-51, 6:52-7:17, claim 1 (disclosing "a second controller [310], responsive to

said second display and user interface [320], said second controller controlling said second controlled device [microscope 300], said second controlled device responsive only to said second controller [310]"); Ex. 1007, Walbrink Decl. at ¶ 60.)

Independent claim 10 combines the fifth, sixth, and seventh elements of independent claim 1 and recites the following elements: "***using a touch panel to communicate a control command associated with the at least one device having non-safety related functions to the second controller***;" "***using the touch panel to communicate a control command associated with the at least one medical device having safety-related functions to the second controller***;" and "***wherein said second controller can only control devices that do not have safety-related functions, and controls the at least one device having non-safety-related functions based on the control command associated therewith received from the touch panel***." Bucholz discloses these elements for the reasons discussed above. (*See* Ex. 1003, Bucholz at 6:11-20, 6:24-26, 6:33-37, 6:52-7:17, 5:43-47, Figs. 1, 2, claim 1; Ex. 1007, Walbrink Decl. at ¶ 60.)

Finally, Bucholz discloses that "***said second controller communicates the control command associated with [said / the] at least one medical device having safety[-]related functions received from [said / the] touch panel to said first controller***," as recited by both claims 1 and 10. Bucholz teaches that, "[b]y

pressing the button marked 'coagulator,' the minibrowser of microscope display and user interface 320 will display the control form for bipolar coagulator 400, and all functions of bipolar coagulator 400 can be manipulated through the control form as displayed on the minibrowser of microscope display and user interface 320." (Ex. 1003, Bucholz at 6:58-7:10.) Display and user interface 320 is driven by embedded controller 310. (*Id.* at 6:18-20 ("Each device is controlled locally using its own embedded controller that drives a display and user interface device.").) Accordingly, when commands for the bipolar coagulator are inputted into display and user interface 320, they are received by embedded controller 310. (Ex. 1007, Walbrink Decl. at ¶ 60.)

Embedded controller 310 ("*said second controller*") then communicates the control command associated with bipolar coagulator 400 ("*said at least one medical device having safety related functions*") received from display and user interface 320 ("*said touch panel*") to embedded controller 410 ("*said first controller*"), which locally controls bipolar coagulator 400 and to which bipolar coagulator 400 is exclusively responsive. (Ex. 1003, Bucholz at 6:16-20 ("[B]ipolar coagulator 400 includes embedded controller 410 . . . . Each device is controlled locally using its own embedded controller that drives a display and user interface device."); *see also id.* at claim 1 (disclosing that "said second controller [310] controls said first controlled device [bipolar coagulator 400] in response to

said second display and user interface [320] by interaction between said first controller [410] and said second controller [310] via said first communications channel, said second communications channel, and said network switch"); Ex. 1007, Walbrink Decl. at ¶ 60.)

Turning then to the dependent claims, Bucholz discloses the additional limitations of dependent claims 2-7 and 9. Due to substantial overlap in claims 4 and 5, those claims are addressed together below.

(ii) Claim 2:

Bucholz discloses that "***said first controller further controls at least one device having non-safety-related functions***." Bucholz further discloses that, in addition to controlling bipolar coagulator 400, embedded controller 410 ("*said first controller*") "drives [the] display and user interface device [420]." (Ex. 1003, Bucholz at 6:18-20.) Display and user interface 420 is a device having non-safety-related functions because its breakdown or failure would not be life-threatening for a patient. (Ex. 1001, '821 patent at 1:54-62.) That is because, if display and user interface 420 failed or had a breakdown during a procedure, the surgeon could use a different interface device within the system, such as the microscope display and user interface 320, to manipulate the settings of the bipolar coagulator 400. (*See* Ex. 1003, Bucholz at 6:58-7:10; Ex. 1007, Walbrink Decl. at ¶ 61.)

(iii) Claim 3:

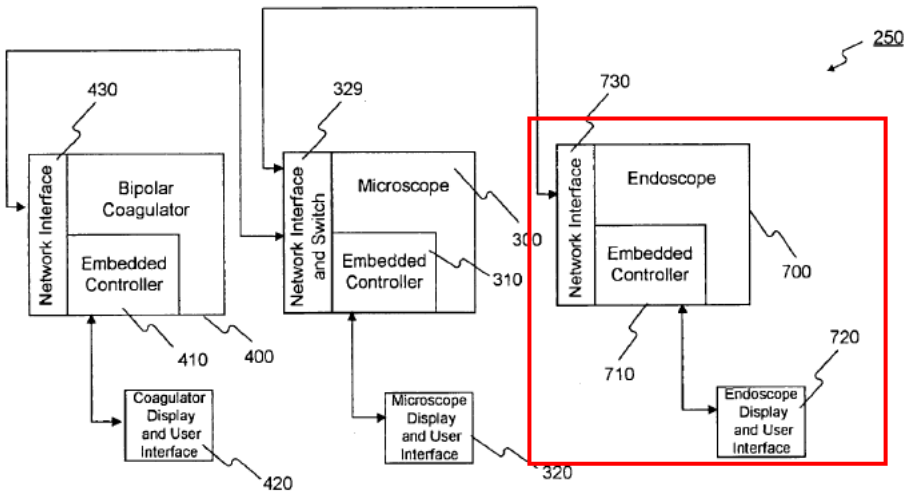
Bucholz discloses that "***said first controller includes embedded operating system software executing thereon***." Bucholz discloses that "[e]ach networked device in the operating room has an embedded controller [including embedded controller 410 ("*said first controller*")] that is Jini-compliant and capable of communication using standard Jini communication protocols over local-area network 200 . . . ." (Ex. 1003, Bucholz at 6:12-15; *see also id.* at 5:8-14.) Embedded controller 410 is also used to locally control bipolar coagulator 410 and to drive display and user interface 420. (*Id.* at 6:16-20.) Bucholz further discloses that "embedded controller 410 has software for a 'minibrowser' 426 (a scaled-down browser) stored in read-only (ROM) along with control forms specific for the device written in the html language." (*Id.* at 6:26-30.) To the extent not expressly disclosed, Bucholz inherently discloses that embedded controller 410 must include embedded operating system software executing thereon in order to enable the controller to interface with and control the operation of these various components connected to it. (Ex. 1007, Walbrink Decl. at ¶ 62.)

In other words, controller 410 and all the components connected thereto, such as bipolar coagulator 400, display and user interface 420, and network interface 430, form a system. (*See id.*) The only way that embedded controller 410 could effectively control the operation of this system is for there to be

operating system software executing thereon. (*See id.*) Without operating system software executing on controller 410, the controller would be unable to effectively handle the diverse functions of the bipolar coagulator, the display, the network communications, etc. (*See id.*) Moreover, this operating system software would necessarily be "embedded" in the controller because it would have to reside in the controller's non-volatile memory. (*See id.*)

(iv) Claims 4 and 5:

Bucholz discloses that "***said at least one device having safety-related functions includes devices for communicating medical imaging data***," and further discloses that "***said at least one device for communicating medical imaging data comprises an endoscopic camera for acquiring images***." Bucholz discloses an endoscope 700, as shown in the Figure 4 below, which is a device having safety-related functions for communicating medical imaging data:

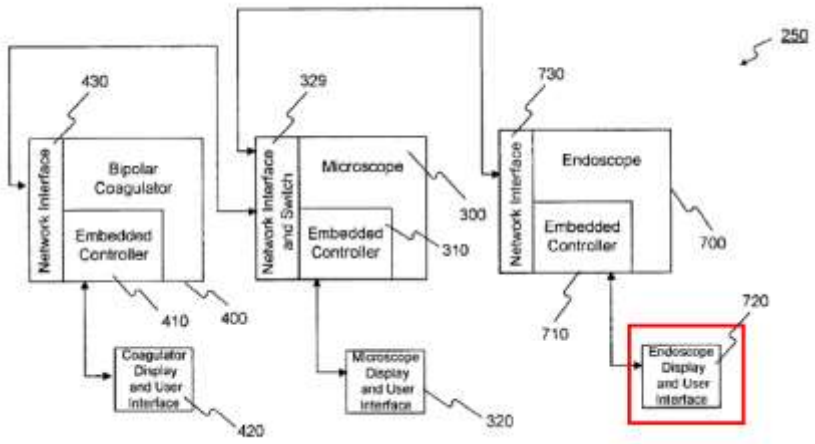


(Ex. 1003, Bucholz at Fig. 4 (annotated); *see also id.* at 7:10-13.) The '821 patent

expressly identifies "endoscopic devices" as one type of "safety-related systems." (Ex. 1001, '821 patent at 1:56-57.) Because endoscope 700 has an embedded controller 710, a display and user interface 720, and a network interface 730, as shown in Figure 4 above, the endoscope could be substituted for the bipolar coagulator into the system described above, and the system would function exactly the same as described above. (*See* Ex. 1003, Bucholz at 9:27-38; Ex. 1007, Walbrink Decl. at ¶ 63.)

(v) Claim 6:

Bucholz discloses that "***said at least one device for communicating medical imaging data further comprises a monitor for displaying images***." Bucholz teaches that "endoscope 700 has an endoscope display and user interface 720," as expressly shown in Figure 4 below:



(Ex. 1003, Bucholz at 7:10-11 (emphasis added), Fig. 4 (annotated).) Bucholz further discloses that "the video produced by networked systems, such as

microscopes and endoscopes, would be encoded by each device and placed onto the network as a data stream. A display or recording device connected to the network would display or record the data stream, respectively." (*Id.* at 8:66-9:4 (emphasis added); Ex. 1007, Walbrink Decl. at ¶ 64.)

(vi) Claim 7:

Bucholz discloses that "***said at least one device having non-safety-related functions includes an image archiving device***." Bucholz discloses that "the video produced by networked systems, such as microscopes and endoscopes, would be encoded by each device and placed onto the network as a data stream. A display or recording device connected to the network would display or record the data stream, respectively." (Ex. 1003, Bucholz at 8:66-9:4 (emphasis added); Ex. 1007, Walbrink Decl. at ¶ 65.)

(vii) Claim 8:

Bucholz discloses that "***said first controller includes voice control software executing thereon***." Bucholz discloses that "[c]ertain devices would have no function unless they were networked, such as, for example . . . a voice recognition unit used to control other devices within the operating room using a program adapted to the surgeon's voice." (Ex. 1003, Bucholz at 7:50-52; Ex. 1007, Walbrink Decl. at ¶ 66.)

(viii) Claim 9:

Bucholz discloses that "***said first controller is connected to said second***

controller via an ethernet bus." Bucholz recites that "the network associated with the operating room may be any type of network known in the art, as for example, a wide-area network or Intranet. Furthermore, although some of the connections between the devices were described as cables, such connections may be wireless, infrared, or any other suitable network known in the art." (Ex. 1003, Bucholz at 11:37-43 (emphasis added).) Bucholz further discloses that "[f]irst networking infrastructure 150 includes local area network 200 and controller 100. Local area network 200 further includes a plurality of exemplary devices, such as microscope 300, bipolar coagulator 400, as well as network switch 128." (*Id.* at 5:20-29 (emphasis added); *see also id.* at 6:52-7:4.) Upon reviewing this disclosure in Bucholz, a person of ordinary skill in the art would know that the combination of local area network 200 and network switch 128 is necessarily referring to an Ethernet-based network. (Ex. 1007, Walbrink Decl. at ¶ 67.) Moreover, the single-line linking network interface 330 and network interface 430 in Figure 1 of Bucholz would signify a bus to a person of ordinary skill. (*See id.*; Ex. 1003, Bucholz at Fig. 1.) Accordingly, even if Bucholz does not expressly disclose this claim element, it inherently discloses it to persons of ordinary skill in the art. (Ex. 1007, Walbrink Decl. at ¶ 67.)

Claim Charts: The below claim charts contain detailed citation to disclosure in Bucholz that anticipates each of claims 1-10 of the '821 patent. Due

to substantial overlap in claims 1 and 10 and claims 4 and 5, those claims, respectively, are addressed together in a single chart.

Claims 1,10	**Bucholz ' 490**
(1) A system for controlling medical devices, comprising: *(10) A method for controlling medical devices, comprising:*	"The present invention relates to an electronic infrastructure for an operating room. More particularly, the present invention relates to a simplified infrastructure for an operating room that allows control of highly complex devices and provides for communication among devices." (Ex. 1003, Bucholz at 1:9-12; *see also id.* at Figs. 1, 4, 5; Ex. 1007, Walbrink Decl. at ¶ 60.)
(1) a first controller; *(1) at least one medical device having safety-related functions controlled by said first controller;* *(10) connecting a first controller to at least one medical device having safety-related functions;*	"[B]ipolar coagulator 400 includes embedded controller 410 . . . . Each device is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:16-20 (emphasis added); *see also id.* at Figs. 1, 4, 6:11-51, 7:10-13; Ex. 1007, Walbrink Decl. at ¶ 60.)
(1) at least one device having non-safety-related functions controlled by said second controller; *(10) connecting a second controller to at least one device having non-safety-related functions;*	"For example, bipolar coagulator 400 includes embedded controller 410, and microscope 300 includes embedded controller 310. Each device is controlled locally using its own embedded controller that drives a display and user interface device." (Ex. 1003, Bucholz at 6:16-20 (emphasis added); *see also id.* at Figs. 1, 4, 6:11-50; Ex. 1007, Walbrink Decl. at ¶ 60.)
(1) a second controller in communication with said first controller; *(10) connecting the first controller to the second*	"The web-like interface allows the device to be controlled by other devices in the operating room. . . . For example, when the network connects two devices, the display of each device could be selected to display the control form of the other connected device. For example, if microscope 300 is

controller;	plugged into local area network 200 along with bipolar coagulator 400, the minibrowser of microscope display and user interface 320 will display a list of other control forms available to it over local area network 200. If the user wants to control the connected device, the same form shown locally for that device's local display would also be displayed on the connected device. By pressing the button marked 'coagulator,' the minibrowser of microscope display and user interface 320 will display the control form for bipolar coagulator 400, and all functions of bipolar coagulator 400 can be manipulated through the control form as displayed on the minibrowser of microscope display and user interface 320." (Ex. 1003, Bucholz at 6:58-7:10 (emphasis added); *see also id.* at Figs. 1, 4; Ex. 1007, Walbrink Decl. at ¶ 60.)
(1) a touch panel that communicates a control command associated with said at least one medical device having safety-related functions and a control command associated with said at least one device having non-safety related functions to said second controller; *(10) using a touch panel to communicate a control command associated with the at least one device having non-safety related functions to the second controller;* *(10) using the touch panel to communicate a control*	(Ex. 1003, Bucholz at Figs. 1, 2, 4 (ref. no. 320); *see also id.* at 5:43-47, 6:16-20 ("Each device is controlled locally using its own embedded controller that drives a display and user interface device."), 6:24-26 ("touch-sensitive flat panel"), 6:58-7:10 ("[T]he minibrowser of microscope display and user interface 320 will display a list of other control forms available to it over local area network 200. If the user wants to control the connected device, the same form shown locally for that device's local display would also be displayed on the connected device. By pressing the button marked 'coagulator,' the minibrowser of microscope display and user interface 320 will display the control form for bipolar coagulator 400 . . . ."); Ex. 1007, Walbrink Decl. at ¶ 60.)

command associated with the at least one medical device having safety-related functions to the second controller;	
(1) wherein said second controller can only control devices that do not have safety-related functions; *(1) wherein said second controller controls said at least one device having non-safety-related functions based on the control command associated therewith received from said touch panel;* *(10) wherein said second controller can only control devices that do not have safety-related functions, and controls the at least one device having non-safety-related functions based on the control command associated therewith received from the touch panel; and*	(Ex. 1003, Bucholz at 6:18-20 ("Each device is controlled locally using its own embedded controller . . . ."); *see also id.* at claim 1 ("said first controlled device responsive only to said first controller" and "said second controlled device responsive only to said second controller" (emphasis added)), 6:33-37 ("When a user touches a button to request a desired task, minibrowser 426 activates embedded controller 410 through an interface so that embedded controller 410 controls bipolar coagulator 400 to perform the desired task."), 6:11-7:17, Figs. 1, 2, 4, 5; Ex. 1007, Walbrink Decl. at ¶ 60.)
(1) wherein said second controller communicates the control command associated with said at least one medical device having safety related functions received from	(Ex. 1003, Bucholz at 6:58-7:10; *see also id.* at 6:16-20, Figs. 1, 2, 4, 5; Ex. 1007, Walbrink Decl. at ¶ 60.)

said touch panel to said first controller. *(10) wherein said second controller communicates the control command associated with the at least one medical device having safety-related functions received from the touch panel to said first controller.*	
Claim 2	**Bucholz**
2. The system of claim 1, wherein said first controller further controls at least one device having non-safety-related functions.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. (Ex. 1003, Bucholz at 6:16-20 ("Each device is controlled locally using its own embedded controller that drives a display and user interface device."); *see also id.* at 6:58-7:10 ("By pressing the button marked 'coagulator,' the minibrowser of microscope display and user interface 320 will display the control form for bipolar coagulator 400 . . . ."); Ex. 1007, Walbrink Decl. at ¶ 61.)
Claim 3	**Bucholz**
3. The system of claim 1, wherein said first controller includes embedded operating system software executing thereon.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. "Each networked device in the operating room has an embedded controller that is Jini-compliant and capable of communication using standard Jini communication protocols over local-area network 200 . . . ." (Ex. 1003, Bucholz at 6:12-15; *see also id.* at 5:8-14.) "Each device is controlled locally using its own embedded controller that drives a display and user interface." (*Id.* at 6:16-20.) "[E]mbedded controller 410 has software for a 'minibrowser' 426 (a scaled-down browser) stored in read-only

	(ROM) along with control forms specific for the device written in the html language." (*Id.* at 6:26-30; Ex. 1007, Walbrink Decl. at ¶ 62.)
Claims 4, 5	**Bucholz**
(4) The system of claim 1, wherein said at least one device having safety-related functions includes devices for communicating medical imaging data. *(5) The system of claim 4, wherein said at least one device for communicating medical imaging data comprises an endoscopic camera for acquiring images.*	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. (Ex. 1003, Bucholz at Fig. 4 ("Endoscope" 700); *see also id.* at 7:10-13, 9:27-38; Ex. 1007, Walbrink Decl. at ¶ 63.)
Claim 6	**Bucholz**
6. The system of claim 5, wherein said at least one device for communicating medical imaging data further comprises a monitor for displaying images.	Bucholz discloses all the elements of claim 5, as discussed above. The analysis of claim 5 is incorporated by reference in its entirety. (Ex. 1003, Bucholz at Fig. 4 ("Endoscope Display and User Interface" 720); *see also id.* at 7:10-11, 8:66-9:4; Ex. 1007, Walbrink Decl. at ¶ 64.)
Claim 7	**Bucholz**
7. The system of claim 6, wherein said at least one device having non-safety-related functions includes an image archiving device.	Bucholz discloses all the elements of claim 6, as discussed above. The analysis of claim 6 is incorporated by reference in its entirety. "[T]he video produced by networked systems, such as microscopes and endoscopes, would be encoded by each device and placed onto the network as a data stream. A display or recording device connected to the network would display or record the data stream, respectively." (Ex. 1003, Bucholz at 8:66-9:4 (emphasis added); Ex. 1007, Walbrink Decl. at ¶ 65.)

Claim 8	Bucholz
8. The system of claim 1, wherein said first controller includes voice control software executing thereon.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. "Certain devices would have no function unless they were networked, such as, for example . . . a voice recognition unit used to control other devices within the operating room using a program adapted to the surgeon's voice." (Ex. 1003, Bucholz at 7:50-52; Ex. 1007, Walbrink Decl. at ¶ 66.)
Claim 9	**Bucholz**
9. The system of claim 1, wherein said first controller is connected to said second controller via an ethernet bus.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. (Ex. 1003, Bucholz at 11:37-43, Fig. 1 ("Local Area Network" 200, "Network switch" 128), 5:20-20, 6:52-7:4; Ex. 1007, Walbrink Decl. at ¶ 67.)

B. Ground 2: Claims 1-10 Are Rendered Obvious Under 35 U.S.C. § 103(a) In View Of Bucholz And The Knowledge Of A Person Of Ordinary Skill In The Art

Bucholz discloses all the elements of claims 1-10, as discussed in § V.A above. To the extent the Board determines, however, that Bucholz fails to expressly or inherently disclose all the elements of claims 1 and 10, and particularly the element requiring that "***said second controller can only control devices that do not have safety-related functions***," Stryker asserts that Bucholz renders these claims obvious under 35 U.S.C. § 103 when considered with the knowledge of one of ordinary skill in the art at the time of the alleged invention. In other words, even if the Board determines that Bucholz fails to anticipate this

element, the element is nevertheless met under § 103 because the differences between it and the disclosure of Bucholz are minor or within the knowledge of one of ordinary skill in the art. *See, e.g., B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582-83 (Fed. Cir. 1996). (Ex. 1007, Walbrink Decl. at ¶ 68.)

Upon reviewing Bucholz, a person of ordinary skill in the art would recognize that Bucholz teaches all of the other elements recited in claims 1 and 10 of the '821 patent, including two separate controllers, controlled devices, a touch screen input device, and communication between the controllers. (*See id.* at ¶ 69.) A person of ordinary skill would further have known how to reconfigure the elements expressly disclosed in Bucholz to achieve the limitations of claims 1 and 10 of the '821 patent. (*See id.*) Specifically, a person of ordinary skill would have known how to modify the Bucholz system so that the second controller therein would only control devices that do not have safety-related functions. (*See id.*)

This modification would have been obvious for at least the following reasons: First, it involves nothing more than the predictable use of prior art elements according to their established functions. (*See id.* at ¶ 70.) Medical device controllers were well known in the art prior to the alleged invention of the '821 patent. (*See id.*) The system claimed in the '821 patent features two controllers being used for their usual, intended purpose—namely, controlling the operation of

other devices, and specifically medical devices in this instance. (*See id.*) The '821 patent merely specifies that the second controller can control only non-safety-related devices, whereas the first controller can control both safety-related and non-safety related devices. (*See id.*) This configuration reflects a design choice: using dedicated controllers for different classes of devices. (*See id.*) At the time of the alleged invention of the '821 patent, a person of ordinary skill who knew how to configure a medical device control system would have known how to separate the devices in the operating room according to their safety- or non-safety-related purposes and connect them to the appropriate dedicated controller. (*See id.*) A person of ordinary skill would have been able to easily achieve this result using known methods of reprogramming the controllers. (*See id.*) In this configuration, each controller would predictably function the same as it would in any other system. (*See id.*)

Moreover, a person of ordinary skill would have been motivated to make this change to the Bucholz system in light of his/her own knowledge of the benefits of prioritizing safety-related systems and processes, which, as discussed above, were well known prior to the alleged invention of the '821 patent. (*See id.* at ¶ 71.) A person of ordinary skill would have reasonably expected this modification to the Bucholz system to work because, as stated above, it entails nothing more than using device controllers according to their usual functions and merely designating

one controller to control only non-safety-related devices. (*See id.*)

Finally, this modification to the Bucholz system would also have been obvious because it results from the use of a known technique to improve a similar system in the same way. (*See id.* at ¶ 72.) Bucholz discloses a medical device control system having multiple controllers. (*See id.*) Isolating the control of non-safety-related devices within the Bucholz system could be viewed as an improvement thereto, given the benefits of prioritizing safety-related processes that were known prior to the alleged invention of the '821 patent. (*See id.*) A person of ordinary skill would have known how to separate the control of the Bucholz devices in this way because it involves nothing more than applying the routine skill required to set up a medical device control system in the first place, and because the controllers would function predictably in the reconfigured system. (*See id.* at ¶¶ 72-73) Petitioner is not aware of any secondary considerations that would tend to show that this combination is non-obviousness—particularly any secondary considerations having a nexus to the claimed inventions. (*See id.* at ¶ 75.)

The additional limitations of claims 2-9, which depend from claim 1, are disclosed in Bucholz, as discussed above in § V.A.

C. Ground 3: Claims 8 And 11 Are Rendered Obvious Under 35 U.S.C. §103(a) In View Of Bucholz In Combination With Brant

Brant in combination with Bucholz would have rendered obvious the additional limitations of the remaining petitioned claims, which are the use of

voice control software executing on the first controller, further comprising the use of a microphone to communicate a control command associated with the at least one medical device having safety-related functions to the first controller (claim 11). Moreover, to the extent the Board determines that Bucholz does not expressly or inherently disclose all of the limitations of claim 8, those limitations can also easily and obviously be found in Brant. In other words, all of the petitioned claims are rendered obvious in view of Bucholz and Brant.

Brant discloses voice control software executing on a controller for controlling medical devices, which further comprises using a microphone to communicate control commands associated with various medical devices to the controller. (Ex. 1004, Brant at 2:12-21.) In particular, Brant discloses "a voice command and control system . . . which can process audio signals from a microphone to identify an operator's verbal commands contained within conversational speech using speech recognition software. The commands are then converted to digital control signals which can be applied to a medical care device." (*Id.*; *see also id.* at 2:38-57, 4:15-33, 6:11-20, 6:43-57, 8:55-57, 10:42-46, 11:6-29, Fig. 2, claim 1; Ex. 1007, Walbrink Decl. at ¶¶ 76-78.)

It would have been obvious to one of ordinary skill in the art at the time of the alleged invention of the '821 patent to combine the voice-control software of Brant and the first controller of Bucholz. (*See* Ex. 1007, Walbrink Decl. at ¶¶ 80-

82.) The benefits of using voice-control software in medical control systems were well known at the time of the alleged invention of the '821 patent. (*See id.*) That is because voice-control software (a) frees surgeons from having to use their hands to control medical devices and/or from having to instruct their assistants how to control the devices; (b) reduces the number of input devices surgeons must use to control the multitude of diverse medical devices within the operating room; (c) enables surgeons to control devices from anywhere in the OR, rather than having to input commands into each medical device's local interface; and (d) enables surgeons to control OR devices without having to shift their attention away from the patient. (*See id.* at ¶ 81.) One of ordinary skill in the art would recognize that the use of voice-control software would greatly enhance surgeons' flexibility and ease of controlling medical devices in the operating room during surgical procedures. (*See id.*)

The prior art also includes a teaching, suggestion or motivation that would lead a person of ordinary skill in the art to include the voice-control software of Brant on the first controller of Bucholz. (*See id.* at ¶¶ 83-84, 87.) Brant teaches that, among other benefits, voice-control software "eliminate[d] the need to perform certain functions such as manipulating instrument panel controls . . . manually, thereby allowing the surgeon 14 and any other attending medical personnel 24 freedom to manipulate devices such as hand-held surgical

tools and foot pedals and other operating room equipment. The system 10 can reduce burdens placed on a surgeon 14 and other medical attendants 24 during a surgical or other medical procedure, and can reduce the number of personnel required in the operating room." (Ex. 1004, Brant at 3:57-66; *see also id.* at 3:49-4:14, 11:7-29.) A person of ordinary skill in the art would be motivated to use the voice-control software of Brant on the first controller of Bucholz, in particular, because voice-control software is most beneficial when used to control the devices most commonly used by a surgeon during a procedure that also require the greatest attention from the surgeon—namely, the safety-related devices. (Ex. 1007, Walbrink Decl. at ¶¶ 83-84, 87.)

In order to combine the voice-control software of Brant with the first controller of Bucholz, a person of ordinary skill would have had to establish a compatible communications link (such as an RS-232, USB, or Ethernet connection) between the voice-control unit and the first controller, which would enable commands to be exchanged between these components. (*See id.* at ¶ 84.) A person of ordinary skill would also have needed to write software to interpret the command outputs from the voice-control unit so that these commands could be passed through the first controller, which would in turn have appropriately controlled the devices according to those commands. (*See id.*) A person of

ordinary skill in the art would have been able to achieve this result based on his/her basic hardware and software knowledge and design experience. (*See id.*)

The combination of the voice-control software disclosed in Brant and the system disclosed in Bucholz would also have been obvious at the time of the alleged invention of the '821 patent because it involves only the predictable use of prior art elements according to their established functions. (*See id.* at ¶ 85.) Brant shows that, at the time of the alleged invention of the '821 patent, it was already well known to use voice-control software and microphones to control medical devices in an operating room. (*See id.*) Brant also expressly discloses voice-control software being executed on medical device controllers. (Ex. 1004, Brant at 4:65-67 ("The computer 18 provides control signals corresponding to an operator's verbal requests to a medical care device 12 via an interface circuit 20.").) As described above, a person of ordinary skill in the art would have known how to combine the voice-control software disclosed in Brant with the first controller disclosed in Bucholz. (Ex. 1007, Walbrink Decl. at ¶ 85.) The voice-control software of Brant would have operated the same in combination with the first controller of Bucholz as it operated with the computer 18 of Brant. (*See id.* at ¶¶ 84-85.) A person of ordinary skill in the art would have recognized that this combination would have led to predictable results because voice-control functionality is simply an add-on feature to a controller that allows the controller to

perform its usual functions while also enabling the controller to receive verbal commands as input. (*See id.* at ¶ 85.)

The combination of the voice-control software and microphones of Brant with the first controller of Bucholz would also have been obvious because it results from the use of a known technique to improve a similar system in the same way. (*See id.* at ¶ 86.) Like Bucholz, Brant discloses a medical device control system. Brant, however, includes an improvement over Bucholz—namely, the use of voice-control software to input commands to the device controller. (*See id.*) For the reasons discussed above, the use of voice-control software in medical device control systems had many recognized benefits prior to the alleged invention of the '821 patent. Furthermore, as discussed above, a person of ordinary skill in the art would have known how to combine the voice-control software of Brant with the first controller in Bucholz to achieve predictable results. (*See id.*)

Petitioner is not aware of any secondary considerations that would tend to show that this combination is non-obviousness—particularly any secondary considerations having a nexus to the claimed inventions. (*See id.* at ¶ 89.)

Claim Charts: The below claim chart contains detailed citation to disclosure in Bucholz and Brant, the combination of which renders obvious claims 8 and 11 of the '821 patent. Due to substantial overlap in claims 8 and 11, those claims are addressed together in a single chart.

Claims 8, 11	Bucholz in Combination with Brant
(8) The system of claim 1, wherein said first controller includes voice control software executing thereon. *(11) The method of claim 10, wherein said first controller includes voice control software executing thereon, further comprising using a microphone to communicate a control command associated with the at least one medical device having safety-related functions to the first controller.*	Bucholz discloses all the elements of claims 1 and 10, as discussed above. The analyses of claims 1 and 10 are incorporated by reference in their entirety. *See above* at claim 8 (§ V.A.vii) for a description of the relevant disclosure in Bucholz. That analysis is incorporated by reference in its entirety. "In accordance with an aspect of the present invention, a voice command and control system is provided which can process audio signals from a microphone to identify an operator's verbal commands contained within conversational speech using speech recognition software. The commands are then converted to digital control signals which can be applied to a medical care device." (Ex. 1004, Brant, at 2:12-21; *see also id.* at 2:38-57, 6:11-20, 6:43-57, 8:55-57, 10:42-46, 11:6-29, Fig. 2, claim 1.) "Operator voice commands are provided to a microphone 26 which is connected to the computer 18. The transduced audio signals received from the microphone 26 are processed in accordance with speech recognition software The system 10 preferably uses Listen® for Windows® version 2.0 by Verbex Voice Systems, Inc., Edison, N.J. The Listen® for Windows® software is user-independent to accommodate many surgeons or operators, without requiring extensive voice training prior to use." (*Id.* at 4:15-33; Ex. 1007, Walbrink Decl. at ¶¶ 76-89.)

D. Ground 4: Claims 3 And 9 Are Rendered Obvious Under 35 U.S.C. §103(a) In View Of Bucholz In Combination With Engleson

To the extent the Board determines that Bucholz does not expressly or inherently disclose all of the limitations of claims 3 and 9, those limitations can also easily and obviously be found in Engleson.

(i) Claim 3:

Engleson discloses a system that automatically manages the administration of patient care, including by collecting patient data and controlling medical devices, through the use of "a number of CPUs having a variety of input and output devices for receiving patient data and for generating or displaying reports. A system of software programs operates on the CPUs to record, process, and produce reports from a database whose data is representative of the care a patient receives in the institution." (*See* Ex. 1005, Engleson at Abstract, 1:5-8, 2:23-52.) Engleson teaches that "[t]he care management system software can be written to operate on a variety of operating systems to suit the needs of a variety of institutions. In a present embodiment, the software is written to interface with the nurses and physicians using the Windows environment (Windows is a trademark of Microsoft, Inc.) on IBM compatible micro-computers. The Windows environment is well-known by those skilled in the art and will not be described in detail herein." (*Id.* at 12:6-21 (emphasis added); *see also id.* at 2:28-38, 4:41-63, 6:30-40, Figs. 2, 3.) Therefore, Engleson discloses "***embedded operating system software***" executing on the CPUs of the patient management system. (Ex. 1007, Walbrink Decl. at ¶¶ 90-94.)

It would have been obvious to one of ordinary skill in the art at the time of the alleged invention of the '821 patent to combine the embedded operating system

software disclosed in Engleson with the first controller of Bucholz. (*See id.* at ¶¶ 95-104.) Bucholz discloses a networking infrastructure for an operating room that allows for the control of medical devices and provides for communication among the devices. (*See id.* at ¶ 96.) The controllers within the Bucholz system serve several functions, such as controlling medical devices, running software for displaying minibrowsers, and handling networking communications. (*See id.*; *see, e.g.*, Ex. 1003, Bucholz at 6:12-15, 6:16-20, 6:26-30.) One of ordinary skill in the art would have looked to the use of embedded operating system software in other applications, including in medical applications such as that disclosed in Engleson, to conclude that such operating systems were an apparent and obvious feature to include on the controllers of Bucholz to enable those controllers to perform their various and diverse system-related tasks. (Ex. 1007, Walbrink Decl. at ¶ 96.) Indeed, a person of ordinary skill would recognize that the embedded controllers of the Bucholz system must include embedded operating system software executing thereon in order to enable the controllers to interface with and control the operation of the various components connected thereto. (*See id.*)

Engleson includes a teaching, suggestion or motivation that would lead a person of ordinary skill in the art to include embedded operating system software on the first controller of Bucholz. (*See id.* at ¶ 97.) In particular, Engleson explains that "[t]he care management system software, when implemented using

the Windows system, is particularly useful in that the Windows operating system provides the ability to load several programs at once." (Ex. 1005, Engleson at 12:14-21.) Accordingly, Engleson provides the motivation to use operating system software in medical applications, such as in the Bucholz system. (Ex. 1007, Walbrink Decl. at ¶ 97.) A person of ordinary skill in the art at the time of the alleged invention of the '821 patent would have had a reasonable expectation of success because operating system software, as well as its interaction with microprocessors, was well understood at the time. (*See id.*) A person of ordinary skill who had worked with medical device controllers and software would have understood how to install and configure embedded operating system software. (*See id.*)

Upon reviewing Engleson, a person of ordinary skill would understand that he/she would have to choose a particular type of operating system software to suit the specific requirements of his/her medical device control system. (*See id.* at ¶ 98.) For instance, some operating system software, such as Windows embedded NT or a dedicated real-time operating system, prevents intervention from outside the operating system, as recognized by the '821 patent. (*See id.*; Ex. 1001, '821 patent at 3:56-59.) On the other hand, some off-the-shelf operating system software, such as certain Windows systems designed for consumer applications, allows for intervention from outside because the system automatically checks for

and downloads software updates from the Internet. (Ex. 1007, Walbrink Decl. at ¶ 98.) A person of ordinary skill in the art would understand that, if it were important to prevent outside intervention into his/her system, then he/she must select a type of operating system software that would not allow for such intervention. (*See id.*) There would have been many such options available to a person of ordinary skill at the time of the alleged invention of the '821 patent. (*See id.*) Bucholz itself recognizes the need to keep control systems safe from outside intervention. (*See id.* at ¶ 99; Ex. 1003, Bucholz, at 4:18-49.)

The combination of the embedded operating system software of Engleson with the first controller of Bucholz would also have been obvious because it involves only the predictable use of prior art elements according to their established functions. (Ex. 1007, Walbrink Decl. at ¶ 100.) Engleson shows that, at the time of the alleged invention of the '821 patent, it was already known to use embedded operating system software in a medical care management system. (*See id.*) A person of ordinary skill in the art would have been able to use known methods to introduce embedded operating system software to the first controller of Bucholz. (*See id.*) Persons of ordinary skill would have known how to select appropriate operating system software that suited the particular needs of the system to run on the first controller of Bucholz. (*See id.*) Incorporating embedded operating system software on a medical device controller requires application of

merely the same techniques that are used in incorporating operating software onto any controller or microprocessor. (*See id.*)

The combination of the embedded operating system software of Engleson and the first controller of Bucholz would also have been obvious because it results from the use of a known technique to improve a similar system in the same way. (*See id.* at ¶ 101.) As discussed above, Bucholz discloses a first controller running operating system software. Similarly, Engleson discloses operating system running on a collection of CPUs in a care management system. Embedded operating system software can be seen as an improvement over off-the-shelf operating system software because it prevents outside intervention and maintains operating system stability, as discussed above. (*See id.*) A person of ordinary skill in the art at the time of the alleged invention of the '821 patent would have known how to select appropriate embedded operating system software to suit the needs of his/her particular medical device control system, as discussed above. Accordingly, a person of ordinary skill would have known how to apply this improvement to his/her medical device control system. (*See id.*)

Finally, the combination of the embedded operating system software of Engleson and the first controller of Bucholz would also have been obvious because it represents a simple substitution of one known element for another to obtain predictable results. (*See id.* at ¶ 102.) As discussed above, Bucholz discloses a

first controller running operating system software. Also as discussed above, the benefits of embedded operating system software were well known in the art at the time of the alleged invention of the '821 patent. (*See id.*) One of ordinary skill in the art would have known how to substitute embedded operating system software for off-the-shelf operating system software in the first controller of Bucholz based on his/her knowledge of operating systems and controllers. (*See id.*) Substituting embedded operating system software for off-the-shelf operating system software involves installing and configuring the embedded operating system software for the particular controller and application. (*See id.*) This requires the routine knowledge of operating system software and controller hardware that would be possessed by a person of ordinary skill in the art. (*See id.*)

Petitioner is not aware of any secondary considerations that would tend to show that this combination is non-obviousness—particularly any secondary considerations having a nexus to the claimed invention. (*See id.* at ¶ 104.)

(ii) Claim 9:

Engleson further discloses that the integrated hospital-wide information and care management system is configured as a local area network and relies on Ethernet cabling to connect various CPUs to the file server of the system. (Ex. 1005, Engleson at 4:23-40, 5:11-13, 14:62-15:10; Ex. 1007, Walbrink Decl. at ¶ 105.)

It would have been obvious to one of ordinary skill in the art at the time of the alleged invention of the '821 patent to combine the Ethernet network disclosed in Engleson with the first controller of Bucholz. (Ex. 1007, Walbrink Decl. at ¶¶ 106-16.) Bucholz itself discloses a networking infrastructure for an operating room that includes both a local area network and a network switch. (*See* Ex. 1003, Bucholz at 5:20-29, 6:52-7:4.). A person of ordinary skill in the art would recognize that these components suggest the use of an Ethernet bus because there are few (if any) types of networks other than Ethernet that use these components together. (Ex. 1007, Walbrink Decl. at ¶ 107.)

Moreover, one of ordinary skill would have looked to the use of Ethernet in other applications, including medical applications like that disclosed in Engleson, to conclude that an Ethernet bus was an apparent and obvious selection to connect the first and second controllers of Bucholz. (*See id.*) At the time of the alleged invention of the '821 patent, Ethernet was a ubiquitous, standardized, reliable, high-quality, low-cost, and robust type of network. (*See id.* at ¶¶ 108-12) One of ordinary skill in the art would recognize that an Ethernet network would provide the reliability and efficiency, as well as the cost efficiency, needed in a medical device control system. (*See id.*)

The combination of the Ethernet network disclosed in Engleson with the controllers disclosed in Bucholz would also have been obvious at the time of the

alleged invention of the '821 patent because it involves only the predictable use of prior art elements according to their established functions. (*See id.* at ¶ 113.) Engleson shows that, at the time of the alleged invention of the '821 patent, it was already known to use ethernet cabling to connect multiple CPUs (which function as controllers) in a medical care management system. (*See id.*) Bucholz discloses that the network between the first and second controllers therein "may be any type of network known in the art, as for example, a wide-area network or Intranet. . . . [S]uch connections may be wireless, infrared, or any other suitable network known in the art." (Ex. 1003, Bucholz at 11:37-43 (emphasis added).) A person of ordinary skill in the art would have known how to establish an Ethernet connection between the first and second controllers in Bucholz because this would involve nothing more than connecting commercially available components, such as an Ethernet interface card, Ethernet cabling, and an Ethernet switch. (Ex. 1007, Walbrink Decl. at ¶ 113.) Once connected via an Ethernet connection, the first and second controllers of Bucholz would communicate with each other in the same way as they would if any other network connection were used between them. (*See id.*) Moreover, there would nothing unique about the Ethernet connection between the first and second controllers; it would be a standard, predictable Ethernet connection. (*See id.*)

Finally, the combination of the Ethernet network disclosed in

Engleson with the controllers disclosed in Bucholz would also have been obvious at the time of the alleged invention of the '821 patent because it results from the use of a known technique to improve a similar system in the same way. (*See id.* at ¶ 114.) Bucholz discloses a network between the first and second controllers therein, which "may be any type of network known in the art, as for example, a wide-area network or Intranet." (Ex. 1003, Bucholz at 11:37-43 (emphasis added).) Similarly, Engleson discloses a network among multiple CPUs in a medical care management system. (Ex. 1005, Engleson at 2:28-36.) As described above, Ethernet was known to have many advantages at the time of the alleged invention of the '821 patent. (Ex. 1007, Walbrink Decl. at ¶ 114.) Accordingly, if the Bucholz system did not already use an Ethernet connection between the first and second controllers, using Ethernet instead could be viewed as an improvement in light of these advantages. (*See id.*) A person of ordinary skill in the art would have known how to establish an Ethernet connection between the first and second controllers in Bucholz because this would involve nothing more than connecting commercially available components. (*See id.*) Therefore, a person of ordinary skill would have known how to improve the Bucholz system by using the Ethernet network disclosed in Engleson between the first and second controllers in Bucholz. (*See id.*)

Petitioner is not aware of any secondary considerations that would tend to

show that this combination is non-obviousness—particularly any secondary considerations having a nexus to the claimed invention. (*See id.* at ¶ 116.)

Claim Charts: The below claim chart contains detailed citation to disclosure in Bucholz and Engleson, the combination of which renders obvious claim 9 of the '821 patent.

Claim 3	Bucholz in Combination with Engleson
3. The system of claim 1, wherein said first controller includes embedded operating system software executing thereon.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. *See above* at claim 3 (§ V.A.iii) for a description of the relevant disclosure in Bucholz. That analysis is incorporated by reference in its entirety. "The care management system software can be written to operate on a variety of operating systems to suit the needs of a variety of institutions. In a present embodiment, the software is written to interface with the nurses and physicians using the Windows environment (Windows is a trademark of Microsoft, Inc.) on IBM compatible micro-computers. The Windows environment is well-known by those skilled in the art and will not be described in detail herein." (Ex. 1005, Engleson at 12:6-21; *see also id.* at 2:28-38, 4:41-63, 6:30-40, Figs. 2, 3; Ex. 1007, Walbrink Decl. at ¶¶ 94-104.)
Claim 9	**Bucholz in Combination with Engleson**
9. The system of claim 1, wherein said first controller is connected to said second controller via an ethernet bus.	Bucholz discloses all the elements of claim 1, as discussed above. The analysis of claim 1 is incorporated by reference in its entirety. *See above* at claim 9 (§ V.A.viii) for a description of the relevant disclosure in Bucholz. That analysis is incorporated by reference in its entirety.

	"Referring now to the drawings, and more particularly to FIG. 1, there is shown generally an integrated hospital-wide information and care management system 30 including one embodiment of the point-of-care management system 30 of the present invention. The care management system embodiment shown in FIG. 1 is depicted as being configured as a local area network with a file server 45 to which are connected a pharmacy computer 60, a nursing station 70, and bedside CPUs 80. The file server 45 stores programs and data input and collected by the various computers in the local area network. Various application modules of the patient management system may be resident in each of the computers in the network and will be discussed in more detail below. Ethernet cabling of a local area network 50 is used to connect various CPUs to the file server." (Ex. 1005, Engleson at 4:23-40 (emphasis added).) "A local area network 50, comprising a thin net, or ethernet cabling is used to connect the central file server 45 to the hardware that comprises the care management system." (*Id.* at 5:11-13; *see also id.* at 14:62-15:10 (emphasis added); Ex. 1007, Walbrink Decl. at ¶¶ 105-16.)

VI. REASONS WHY PROPOSED GROUNDS ARE NON-REDUNDANT

Petitioner respectfully submits that each of the above-proposed grounds is non-redundant. For example, Bucholz is the only reference for which Petitioner offers an anticipation ground. Brant is the only reference for which Petitioner offers an obviousness rationale based on adding the claimed "***voice control software***" and "***microphone***" elements of dependent claim 11. Finally, Engleson is the only reference for which Petitioner offers an obviousness rationale based on adding the claimed "***embedded operating system software***" element of dependent

claim 3 and the claimed "***ethernet bus***" element of dependent claim 9.

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 1-11 of the '821 patent.

Respectfully submitted,

Dated: February 18, 2015

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,439,821 and Exhibits 1001-1007 were served on February 18, 2015 by Federal Express on the following attorney of record listed on PAIR:

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