

17667
111705
U.S. PTO

**UTILITY
PATENT APPLICATION
TRANSMITTAL**

Our Docket No.: **B819.12-0004**

Date: **November 17, 2005**

First Named Inventor: **Minh Quang Hoang**

Title: **PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL
CAP/CLEANER**

Express Mail No.: **EV655619585US**

113002 U.S. PTO
11/28/11
111705

APPLICATION ELEMENTS

**ADDRESS TO: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

1. ☒ Fee Calculation Sheet
(Submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status
3. ☒ Specification Total Pages **[12]**
 - Descriptive title of the invention
 - Cross References to Related Applications
 - Statement Regarding Fed. Sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
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 - Abstract of the Disclosure
4. ☒ Drawings (35 U.S.C. 113) Total Sheets **[7]**
5. ☒ Oath or Declaration Total Pages **[2]**
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i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b)
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ACCOMPANYING APPLICATION PARTS

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18. If a **CONTINUING APPLICATION**, check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Division ☐ Continuation-in-part (CIP) of prior Application No.

Prior Application Information: Examiner Group Art Unit

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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ATTY NAME
AND REG. NO.

**David R. Fairbairn
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SIGNATURE:

David R. Fairbairn

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**Kinney & Lange, P.A.
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312 South Third Street
Minneapolis, MN 55415-1002**

TELEPHONE

(612) 339-1863

FAX: **(612) 339-6580**

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1. ☒ The Commissioner is hereby authorized to charge any additional fee required under 37 C.F.R. 1.16 and 1.17 and credit any over payments to Deposit Account <u>No.11-0982</u>. Deposit Account Name: Kinney & Lange, P.A. A duplicate copy of this communication is enclosed. 2. ☒ Check Enclosed	3. ADDITIONAL FEES <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee Code</th> <th>Small Entity Fee Code</th> <th>Fee (\$)</th> <th>Fee (\$)</th> <th>Fee Description</th> <th>Fee paid</th> </tr> </thead> <tbody> <tr><td>1051</td><td>130</td><td>2051</td><td>65</td><td>Surcharge - Late filing fee or oath</td><td>—</td></tr> <tr><td>1052</td><td>50</td><td>2052</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td>—</td></tr> <tr><td>1053</td><td>130</td><td>1053</td><td>130</td><td>Non-English specification</td><td>—</td></tr> <tr><td>1812</td><td>2,520</td><td>1812</td><td>2,520</td><td>For Filing a Request for Reexamination</td><td>—</td></tr> <tr><td>1251</td><td>120</td><td>2251</td><td>60</td><td>Extension for reply within first month</td><td>—</td></tr> <tr><td>1252</td><td>450</td><td>2252</td><td>225</td><td>Extension for reply within second month</td><td>—</td></tr> <tr><td>1253</td><td>1,020</td><td>2253</td><td>510</td><td>Extension for reply within third month</td><td>—</td></tr> <tr><td>1254</td><td>1,590</td><td>2254</td><td>795</td><td>Extension for reply within fourth month</td><td>—</td></tr> <tr><td>1255</td><td>2,160</td><td>2255</td><td>1,080</td><td>Extension for reply within fifth month</td><td>—</td></tr> <tr><td>1402</td><td>500</td><td>2402</td><td>250</td><td>Filing a brief in support of an appeal</td><td>—</td></tr> <tr><td>1403</td><td>1,000</td><td>2403</td><td>500</td><td>Request for oral hearing</td><td>—</td></tr> <tr><td>1814</td><td>130</td><td>2814</td><td>65</td><td>Terminal Disclaimer Fee</td><td>—</td></tr> <tr><td>1452</td><td>500</td><td>2452</td><td>250</td><td>Petition to revive - unavoidable</td><td>—</td></tr> <tr><td>1453</td><td>1,500</td><td>2453</td><td>750</td><td>Petition to revive - unintentional</td><td>—</td></tr> <tr><td>1501</td><td>1,400</td><td>2501</td><td>700</td><td>Utility/Reissue issue fee</td><td>—</td></tr> <tr><td>1502</td><td>800</td><td>2502</td><td>400</td><td>Design issue fee</td><td>—</td></tr> <tr><td>1460</td><td>130</td><td>1460</td><td>130</td><td>Petitions to the Commissioner</td><td>—</td></tr> <tr><td>1807</td><td>50</td><td>1807</td><td>50</td><td>Petitions related to provisional applications</td><td>—</td></tr> <tr><td>1806</td><td>180</td><td>1806</td><td>180</td><td>Submission of Information Disclosure Statement</td><td>—</td></tr> <tr><td>8021</td><td>40</td><td>8021</td><td>40</td><td>Recording each patent assignment per property (times number of properties)</td><td>40</td></tr> <tr><td>1801</td><td>790</td><td>2801</td><td>395</td><td>Request for Continued Examination (RCE)</td><td>—</td></tr> <tr><td colspan="5">Other fee (specify) _____</td><td>—</td></tr> <tr> <td colspan="5" style="text-align: right;">Subtotal (3) \$40.00</td> </tr> </tbody> </table>	Large Entity Fee Code	Small Entity Fee Code	Fee (\$)	Fee (\$)	Fee Description	Fee paid	1051	130	2051	65	Surcharge - Late filing fee or oath	—	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	—	1053	130	1053	130	Non-English specification	—	1812	2,520	1812	2,520	For Filing a Request for Reexamination	—	1251	120	2251	60	Extension for reply within first month	—	1252	450	2252	225	Extension for reply within second month	—	1253	1,020	2253	510	Extension for reply within third month	—	1254	1,590	2254	795	Extension for reply within fourth month	—	1255	2,160	2255	1,080	Extension for reply within fifth month	—	1402	500	2402	250	Filing a brief in support of an appeal	—	1403	1,000	2403	500	Request for oral hearing	—	1814	130	2814	65	Terminal Disclaimer Fee	—	1452	500	2452	250	Petition to revive - unavoidable	—	1453	1,500	2453	750	Petition to revive - unintentional	—	1501	1,400	2501	700	Utility/Reissue issue fee	—	1502	800	2502	400	Design issue fee	—	1460	130	1460	130	Petitions to the Commissioner	—	1807	50	1807	50	Petitions related to provisional applications	—	1806	180	1806	180	Submission of Information Disclosure Statement	—	8021	40	8021	40	Recording each patent assignment per property (times number of properties)	40	1801	790	2801	395	Request for Continued Examination (RCE)	—	Other fee (specify) _____					—	Subtotal (3) \$40.00				
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Signature David R. Fairbairn Reg. No. 26,047

Date 11/17/05 Deposit Account No. 11-0982

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: Minh Quang Hoang	
Appln. No.	:	
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Title	: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	Examiner:
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EXPRESS MAIL COVER SHEET

Commissioner For Patents
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SENT VIA EXPRESS MAIL

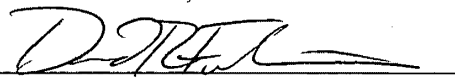
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The following papers are being transmitted via **EXPRESS MAIL** to the U.S. Patent and Trademark Office on the date shown below:

1. Fee Calculation Form with attached checks for \$1,100.00 and \$40.00;
2. Utility Patent Application Transmittal;
3. Utility Patent Application (12 pages);
4. Drawings (7 sheets);
5. Declaration;
6. Patent Recordation Cover Sheet;
7. Assignment; and
8. File Data Form.

Respectfully submitted,
KINNEY & LANGE, P.A.

Date: 11/17/05

By 
David R. Fairbairn, Reg. No. 26,047
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
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DRF:CJB:kmm

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Total Amount of Payment \$ 1,140.00		Atty. Docket Number	B819.12-0004

METHOD OF PAYMENT (Check One)	FEE CALCULATION (Continued)																																																																																																																																															
1. ☒ The Commissioner is hereby authorized to charge any additional fee required under 37 C.F.R. 1.16 and 1.17 and credit any over payments to Deposit Account <u>No.11-0982</u>. Deposit Account Name: Kinney & Lange, P.A. A duplicate copy of this communication is enclosed. 2. ☒ Check Enclosed	3. ADDITIONAL FEES <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee Code</th> <th>Small Entity Fee Code</th> <th>Fee (\$)</th> <th>Fee (\$)</th> <th>Fee Description</th> <th>Fee paid</th> </tr> </thead> <tbody> <tr><td>1051</td><td>130</td><td>2051</td><td>65</td><td>Surcharge - Late filing fee or oath</td><td>—</td></tr> <tr><td>1052</td><td>50</td><td>2052</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td>—</td></tr> <tr><td>1053</td><td>130</td><td>1053</td><td>130</td><td>Non-English specification</td><td>—</td></tr> <tr><td>1812</td><td>2,520</td><td>1812</td><td>2,520</td><td>For Filing a Request for Reexamination</td><td>—</td></tr> <tr><td>1251</td><td>120</td><td>2251</td><td>60</td><td>Extension for reply within first month</td><td>—</td></tr> <tr><td>1252</td><td>450</td><td>2252</td><td>225</td><td>Extension for reply within second month</td><td>—</td></tr> <tr><td>1253</td><td>1,020</td><td>2253</td><td>510</td><td>Extension for reply within third month</td><td>—</td></tr> <tr><td>1254</td><td>1,590</td><td>2254</td><td>795</td><td>Extension for reply within fourth month</td><td>—</td></tr> <tr><td>1255</td><td>2,160</td><td>2255</td><td>1,080</td><td>Extension for reply within fifth month</td><td>—</td></tr> <tr><td>1402</td><td>500</td><td>2402</td><td>250</td><td>Filing a brief in support of an appeal</td><td>—</td></tr> <tr><td>1403</td><td>1,000</td><td>2403</td><td>500</td><td>Request for oral hearing</td><td>—</td></tr> <tr><td>1814</td><td>130</td><td>2814</td><td>65</td><td>Terminal Disclaimer Fee</td><td>—</td></tr> <tr><td>1452</td><td>500</td><td>2452</td><td>250</td><td>Petition to revive - unavoidable</td><td>—</td></tr> <tr><td>1453</td><td>1,500</td><td>2453</td><td>750</td><td>Petition to revive - unintentional</td><td>—</td></tr> <tr><td>1501</td><td>1,400</td><td>2501</td><td>700</td><td>Utility/Reissue issue fee</td><td>—</td></tr> <tr><td>1502</td><td>800</td><td>2502</td><td>400</td><td>Design issue fee</td><td>—</td></tr> <tr><td>1460</td><td>130</td><td>1460</td><td>130</td><td>Petitions to the Commissioner</td><td>—</td></tr> <tr><td>1807</td><td>50</td><td>1807</td><td>50</td><td>Petitions related to provisional applications</td><td>—</td></tr> <tr><td>1806</td><td>180</td><td>1806</td><td>180</td><td>Submission of Information Disclosure Statement</td><td>—</td></tr> <tr><td>8021</td><td>40</td><td>8021</td><td>40</td><td>Recording each patent assignment per property (times number of properties)</td><td>40</td></tr> <tr><td>1801</td><td>790</td><td>2801</td><td>395</td><td>Request for Continued Examination (RCE)</td><td>—</td></tr> <tr><td colspan="5">Other fee (specify) _____</td><td>—</td></tr> <tr> <td colspan="5" style="text-align: right;">Subtotal (3) \$40.00</td> </tr> </tbody> </table>	Large Entity Fee Code	Small Entity Fee Code	Fee (\$)	Fee (\$)	Fee Description	Fee paid	1051	130	2051	65	Surcharge - Late filing fee or oath	—	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	—	1053	130	1053	130	Non-English specification	—	1812	2,520	1812	2,520	For Filing a Request for Reexamination	—	1251	120	2251	60	Extension for reply within first month	—	1252	450	2252	225	Extension for reply within second month	—	1253	1,020	2253	510	Extension for reply within third month	—	1254	1,590	2254	795	Extension for reply within fourth month	—	1255	2,160	2255	1,080	Extension for reply within fifth month	—	1402	500	2402	250	Filing a brief in support of an appeal	—	1403	1,000	2403	500	Request for oral hearing	—	1814	130	2814	65	Terminal Disclaimer Fee	—	1452	500	2452	250	Petition to revive - unavoidable	—	1453	1,500	2453	750	Petition to revive - unintentional	—	1501	1,400	2501	700	Utility/Reissue issue fee	—	1502	800	2502	400	Design issue fee	—	1460	130	1460	130	Petitions to the Commissioner	—	1807	50	1807	50	Petitions related to provisional applications	—	1806	180	1806	180	Submission of Information Disclosure Statement	—	8021	40	8021	40	Recording each patent assignment per property (times number of properties)	40	1801	790	2801	395	Request for Continued Examination (RCE)	—	Other fee (specify) _____					—	Subtotal (3) \$40.00				
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Signature  Reg. No. 26,047

Date 11/17/05 Deposit Account No. 11-0982

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Minh Quang Hoang	
Appln. No. :	
Filed : November 17, 2005	Group Art Unit:
Title : PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	Examiner:
Docket No. : B819.12-0004	

EXPRESS MAIL COVER SHEET

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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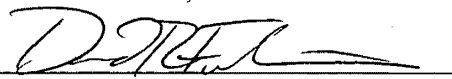
Express Mail No.: 11 EV655619585US

The following papers are being transmitted via **EXPRESS MAIL** to the U.S. Patent and Trademark Office on the date shown below:

1. Fee Calculation Form with attached checks for \$1,100.00 and \$40.00;
2. Utility Patent Application Transmittal;
3. Utility Patent Application (12 pages);
4. Drawings (7 sheets);
5. Declaration;
6. Patent Recordation Cover Sheet;
7. Assignment; and
8. File Data Form.

Respectfully submitted,
KINNEY & LANGE, P.A.

Date: 11/17/05

By 
David R. Fairbairn, Reg. No. 26,047
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

DRF:CJB:kmm

PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

BACKGROUND OF THE INVENTION

5 Catheter-related bloodstream infections are caused by bacteria/fungi in patients with intravascular catheters. These infections are an important cause of illness and excess medical costs, as approximately 80,000 catheter-related bloodstream infections occur in U.S. intensive care units each year. In addition to the monetary costs, these infections are associated with anywhere from 2,400 to
10 20,000 deaths per year.

Guidelines from the Centers for Disease Control and Prevention describe various ways to limit catheter-related bloodstream infections in hospital, outpatient and home care settings. The guidelines address issues such as hand hygiene, catheter site care and admixture preparation. Despite these guidelines,
15 catheter-related bloodstream infections continue to plague our healthcare system.

Impregnating catheters with various antimicrobial agents is one approach that has been implemented to prevent these infections. These catheters, however, have given less than satisfactory results. In addition, some microbes have developed resistance to the various antimicrobial agents in the system.

20 In another system that is commercially available in Europe, a catheter hub containing an antiseptic chamber is filled with three percent iodinated alcohol. Though it has shown to be effective, the catheter hub is expensive and does not fare as well in a formal cost-benefit analysis. Therefore, there is a need for an effective and inexpensive way to reduce the number of catheter-related
25 infections.

BRIEF SUMMARY OF THE INVENTION

The present invention is a device for antiseptically maintaining a patient fluid line access valve. The device includes a housing for covering the access portion of the access valve. A pad within the housing contacts the surface of
30 the access portion of the access valve prior to (and optionally after) accessing the

patient fluid line via the access valve to reduce the amount of microbes on the valve's access portion.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded view of a first representative embodiment of
5 a cap/cleaner device and a patient fluid line access valve.

Figure 2 is a cross-sectional side view of the first representative embodiment of the cap/cleaner device.

Figure 3 is a cross-sectional side view of the first cap/cleaner device capping a patient fluid line access valve.

10 Figure 4 is a cross-sectional side view of the first cap/cleaner device cleaning a patient fluid line access valve.

Figure 5 is a flow chart illustrating representative embodiments of methods of using the cap/cleaner device.

15 Figure 6 is a perspective view of a second representative embodiment of a cap/cleaner device.

Figure 7 is a cross-sectional side view of the second cap/cleaner device.

Figure 8 is a cross-sectional view of a first separable connector.

Figure 9 is a side view of a second separable connector.

20 Figure 10A is a cross-sectional view of cleaning device.

Figure 10B is a cross-sectional view of a capping device.

DETAILED DESCRIPTION

Figure 1 shows an exploded view of patient fluid line access valve cap/cleaner device 10 with patient fluid line access valve A and patient fluid line B.

25 Cap/cleaner 10 includes housing 12 with cap end 14, cleaning end 16 and thread 18; and lid 20. Access valve A includes housing A2 with thread A4 and septum A6 with slit A8. The exposed surface of septum A6 along with at least a portion of the exposed surface of housing A2 that surrounds septum A6, form access portion A10

of access valve A. Line B may be any of a number of types that include, for example, intravascular (IV) lines and catheters, saline wells, arterial lines and hemodialysis lines.

As will be described in more detail below, cap end 14 of cap/cleaner 10
5 attaches to access portion A10 of access valve A. Housing 12 is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, glycol-modified polyethylene terephthalate, acrylonitrile butadiene styrene or any other moldable plastic material used in medical devices.

Cap end 14 of housing 12 is open and contains thread 18 along the inside of
10 the opening. Cleaning end 16 is covered by lid 20. Lid 20 is typically made of foil or similar type material and completely seals the opening (not shown) of cleaning end 16. Any type of material or seal may be used as long as a moisture barrier is provided.

Figure 2 shows cap/cleaner 10 in more detail. In addition to the structures
15 shown in Figure 1, cap/cleaner 10 also includes internal wall 12a, hood 16a and chamber 16b of cleaning end 16, cap 14a and cavity 14b of cap end 14, wet pad 22 within chamber 16b and dry pad 24 within cavity 14b. Internal wall 12a separates cap end 14 and cleaning end 16.

Cap/cleaner 10 is typically distributed and stored in a sterile, sealed package
20 either alone or paired with a patient fluid line access valve. One such type of valve is the BD Q-Syte™ valve from Becton, Dickinson and Company (illustrated in Figure 1). However, cap/cleaner 10 is useful with any type of needleless or needle-required access valve. Once removed from the package, cap/cleaner 10 is ready for use.

25 Figure 3 illustrates cap/cleaner 10 covering access portion A10 of access valve A. Septum A6 provides an accessible seal for either a needle or a male luer taper. In the case of a needleless access device, such as that shown in Figure 3, slit A8 extends through septum A6 to provide a port for insertion of the male luer taper.

As shown, cap end 14 includes cap 14a with cavity 14b, which contains dry pad 24. Dry pad 24 is impregnated with an antimicrobial agent to aid in maintaining antiseptic conditions of access portion A10 of valve A. Suitable material for dry pad 24 includes non-woven material or a foam sponge pad made of polyurethane, polyester, cotton or any bioengineered plastic material such as silicone. Any of a number of antimicrobial agents may be used to impregnate dry pad 24. Some examples include chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Alternatively, cap end 14 does not contain dry pad 24 and aids in maintaining antiseptic conditions by simply covering access portion A10.

In use, cap end 14 of cap/cleaner 10 is placed over access portion A10 such that access portion A10 is within cavity 14b of cap end 14. Cap/cleaner 10 may be attached either prior to or after placement of valve A for the patient. As shown in Figure 3, valve A includes thread A4. By rotating cap/cleaner 10 or valve A relative to one another, threads A4 and 18 (of cap/cleaner 10) interlock to provide a secured attachment. It is not necessary, however, for valve A to include thread A4. Cap end 14 will also attach and hold a luer slip, which does not have a thread. In other embodiments, cap/cleaner 10 may be manufactured without a thread.

The amount of material used for dry pad 24 can vary. Typically, there is enough material for dry pad 24 to contact at least septum A6 of valve A. Enough space should be left in cavity 14b of cap end 14 for access portion A10 of valve A to be encompassed by cap end 14, thus, maintaining antiseptic conditions of the surface. By maintaining antiseptic conditions of the surface, the risk of microbes penetrating into valve A is minimized.

To further minimize the opportunity for penetration by microbes, access portion A10 is cleaned prior to accessing valve A with a needle or male luer taper. Figure 4 illustrates cap/cleaner 10 cleaning access portion A10 of valve A.

As shown in Figure 4, cleaning end 16 includes hood 16a and chamber 16b, which contains wet pad 22. Wet pad 22 is impregnated with a cleaning agent and optionally, an antimicrobial agent. Wet pad 22 may be made from materials similar to those described for dry pad 24.

5 The cleaning solution is typically an alcohol- or water-based solution. A suitable alcohol-based solution contains about 50% to about 100% (no additional water) of an alcohol solution. The balance of solutions that are less than 100% alcohol contain water and other optional materials such as fragrance, dye, surfactant, emollient, etc.

10 Suitable water-based solutions contain about 1% to about 10% alcohol solvent as a wetting agent and about 90% to about 99% water. Again, optional materials may also be added such fragrance, dye, surfactant, emollient, etc.

 In an alternative embodiment, the cleaning solution also includes an antimicrobial agent. Any of a number of antimicrobial agents may be used in wet
15 pad 22. Some examples include chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Wet pad 22 and dry pad 24 may be impregnated with the same or different antimicrobial agents.

 As shown in the Figures, cleaning end 16 is larger than cap end 14. The
20 hood of cleaning end 16 loosely encompasses at least access portion A10 of valve A, and chamber 16b is sized to allow some movement when access portion A10 is inserted. The amount of material used for wet pad 22 will vary, but the amount should hold enough cleaning solution and allow enough movement for thorough cleaning. Wet pad 22 should be contained entirely within hood 16a such that it is
25 recessed inside chamber 16b of cleaning end 16.

 In preparation for accessing valve A, cap end 14 is removed from valve A either by rotating cap/cleaner 10 to release threads 18 and A4 or by simply pulling if valve A does not have a thread. Lid 20 is removed from cleaning end 16. Cleaning

end 16 is then placed over at least access portion A10, such that wet pad 22 contacts septum A6. Though Figure 4 only shows contact with septum A6, additional pressure may be applied such that wet pad 22 extends beyond the edges of septum A6 to contact portions of the exposed surface of housing A2.

5 Next, for thorough cleaning, wet pad 22 should scrub access portion A10 of valve A. Scrubbing may be accomplished by, for example, rotational movement or back and forth movement. Scrubbing should be carried out for a time long enough to allow the cleaning solution to at least disinfect access portion A10 of valve A.

10 Once cleaned, valve A is ready to use. A needle or male luer taper is inserted to either infuse or withdraw fluid from the patient fluid line.

Figure 5 is a flowchart illustrating representative embodiments of methods for using cap/cleaner 10. Capping step 34, cleaning step 36 and accessing step 38 were described above and are the same in each embodiment. However, upon withdrawal after accessing the patient fluid line, access portion A10 of valve A may
15 either be immediately capped or cleaned again prior to capping. If immediately capped, a new, second cap/cleaner 10a is obtained and removed from its package. This is represented by step 40. Cap end 14 of cap/cleaner 10a is placed over access portion A10 as described above. Cleaning end 16 of cap/cleaner 10a is sealed and ready for the next time valve A is utilized.

20 Alternatively, access portion A10 may be cleaned again prior to capping. This can be performed in one of the following ways. First, in step 42, cleaning end 16 of cap/cleaner 10 is reused to clean access portion A10, which is then capped, at step 44, with cap end 14 of a new, second cap/cleaner 10a. Second, in step 46, cleaning end 16 of a new, second cap/cleaner 10a is used to clean access portion
25 A10. Then, valve A may be capped either with cap end 14 of cap/cleaner 10a (step 48) or of a new, third cap/cleaner 10b (step 50). Third, in step 52, access portion A10 may be cleaned with an alternative disposable cleaning device that is well known in the art. Examples of such cleaning devices include alcohol wipes, iodine

swabs, etc. Once cleaned, cap end 14 of a new, second cap/cleaner 10a may be attached to valve 26 (step 50).

Additional embodiments of the present invention include separable and individual, uncoupled devices. Figure 6 shows separable cap/cleaner 56. Separable
5 cap/cleaner 56 includes cap end 58, cleaning end 60 and gap 62. Gap 62 is the separation between cap end 58 and cleaning end 60.

Figure 7 shows separable cap/cleaner 56 in more detail and further includes dry pad 64 within cap end 58, wet pad 66 within cleaning end 60 and breakable connector 68. In use, separable cap/cleaner 56 operates as described above for
10 cap/cleaner 10 except that cleaning end 60 may be removed after cleaning access portion A10 of valve A. Detaching cleaning end 60 reduces bulkiness from separable cap/cleaner 56 by only maintaining cap end 58 over access portion A10.

Figure 8 shows a representative embodiment of breakable connector 68. Connector 68 is typically made of the same material from which housing 12 is
15 fabricated. Torsional shearing caused by twisting cap end 58 and/or cleaning end 60 relative to each other may be used to break connector. Alternatively, a three-point bending force, which consists of a fulcrum (connector 68) that directs a force vector contralateral to the direction of the terminal (cap end 58 and cleaning end 60) force vectors, may be applied for breaking connector 68. Once removed, cleaning
20 end 60 may be discarded.

Figure 9 is an alternate embodiment showing notched breakable connector 70. Notch 72 within connector 70 is an area of reduced cross-sectional area, which acts as a score to facilitate breaking of connector 70.

Other separation mechanisms may also be used to remove cleaning end 60
25 from cap end 58. For instance, a luer lock type mechanism can be utilized to separate ends 58 and 60 from each other.

Figure 10A shows a representative embodiment of cleaning device 74 with lid 74a and wet pad 76. Here, cleaning device 74 is a stand-alone device that is used as described above for cleaning end 16.

Figure 10B shows a representative embodiment of cap device 78 with lid 78a and pad 80. Cap device 78 is a stand-alone device where pad 80 may either be a wet pad or a dry pad. Where pad 80 is a dry pad, cap device 78 is used as described above for cap end 14.

Where pad 80 is a wet pad, cap device 78 may be used to clean access portion A10 of valve A in addition to its capping function. The twisting motion involved in removing and placing cap device 78 with respect to access portion A10 provides friction for cleaning. Additional cleaning can be accomplished by twisting cap device 78 in one direction and then in the reverse direction for a desired amount of time.

With either cleaning device 74 or cap device 78, additional gripping surface may be added by extending the length of the housing. The increased gripping surface would provide easier handling of devices 74 and 78.

Cap/cleaner 10 cleans and maintains access valves in antiseptic or aseptic condition. This substantially decreases the risk of patient infections caused by the ingress of microbes into the access valves, particularly for needleless access valves.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

CLAIMS:

1. A device for antiseptically maintaining a patient fluid line access valve, the device comprising:
 - a housing for covering an access portion of the access valve; and
 - a pad within the housing for contacting an access portion of the access valve to reduce the amount of microbes on the access portion.
2. The device of claim 1 wherein the housing further comprises:
 - a cap with a cavity for covering the access portion;
 - wherein the pad is within the cavity of the cap.
3. The device of claim 2 wherein the pad is impregnated with an antimicrobial agent.
4. The device of claim 2 wherein the cap includes a thread within the cavity.
5. The device of claim 2 wherein the pad is one of a dry pad and a wet pad.
6. The device of claim 5 wherein the wet pad contains a cleaning solution.
7. The device of claim 1 wherein the housing further comprises:
 - a hood with a chamber for covering the access portion;
 - wherein the pad is a wet pad within the chamber.
8. The device of claim 7 wherein the wet pad contains a cleaning solution.
9. The device of claim 8 wherein the wet pad contains an antimicrobial agent.

10. The device of claim 1 and further comprising:
a lid sealing the pad within the housing.
11. A device for reducing risk of contamination of a patient fluid line access valve, the device comprising:
means for cleaning an access portion of the access valve with a cleaning solution;
means for covering the access portion of the access valve; and
means for coupling the means for cleaning and the means for covering.
12. The device of claim 11 wherein the means for coupling comprises a housing.
13. The device of claim 11 wherein the means for coupling comprises a separable connector.
14. The device of claim 11 and further comprising:
means for retaining an antimicrobial agent within the means for covering.
15. The device of claim 11 and further comprising:
means for securing the means for covering to the access valve.
16. The device of claim 11 and further comprising:
means for sealing the means for cleaning.
17. A method of reducing risk of contamination of a patient fluid line access valve, the method comprising:

attaching a first cap of a first device to an access portion of the access valve;
cleaning the access portion of the access valve with a first wet pad of the
first device prior to accessing the patient fluid line; and
attaching a second cap of a second device to the access portion of the access
valve after accessing the patient fluid line.

18. The method of claim 17 and further comprising:
cleaning the access portion of the access valve with the first wet pad of the
first device after accessing the patient fluid line.
19. The method of claim 17 and further comprising:
cleaning the access portion of the access valve with a second wet pad of the
second device after accessing the patient fluid line.
20. The method of claim 17 and further comprising:
cleaning the access portion of the access valve with one of an alcohol wipe
and iodine swab after accessing the patient fluid line.
21. The method of claim 17 wherein the first cap of the first device is attached
to the access portion of the access valve after placement of a catheter and the access
valve for a patient.
22. The method of claim 17 wherein the first cap of the first device is attached
to the access portion of the access valve prior to placement of a catheter and the
access valve for a patient.

PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

ABSTRACT OF THE DISCLOSURE

Cap and cleaning devices antiseptically maintain patient fluid line access valves to minimize the risk of infection via catheters. The devices have a cap that may contain a dry pad impregnated with an antimicrobial agent. The cap covers the access portion of the access valve when not in use. The devices have a hood that contains a wet pad impregnated with a cleaning solution and, optionally, an antimicrobial agent. The wet pad cleans the access portion of the access valve prior to and optionally, after the access valve is utilized to access the patient fluid line.

FIG. 1

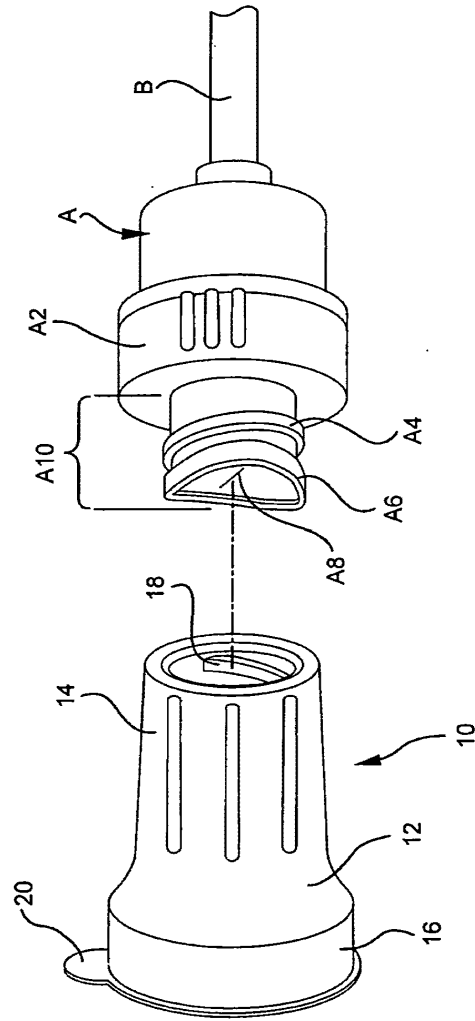


FIG. 2

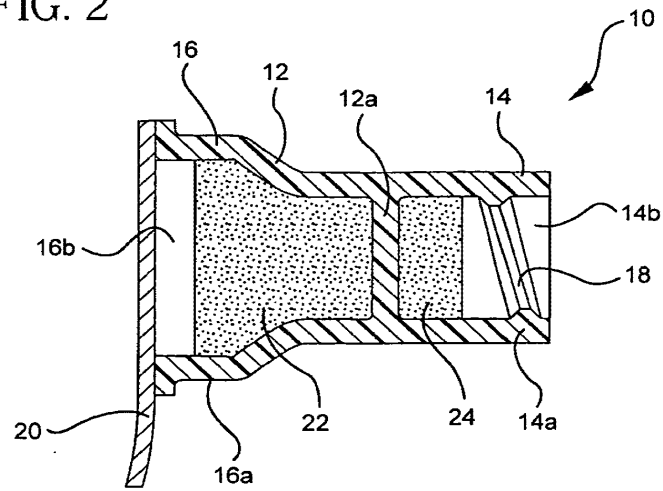


FIG. 3

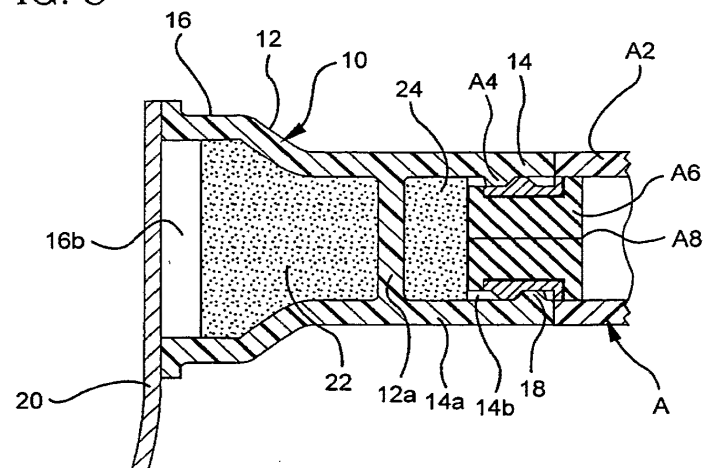


FIG. 4

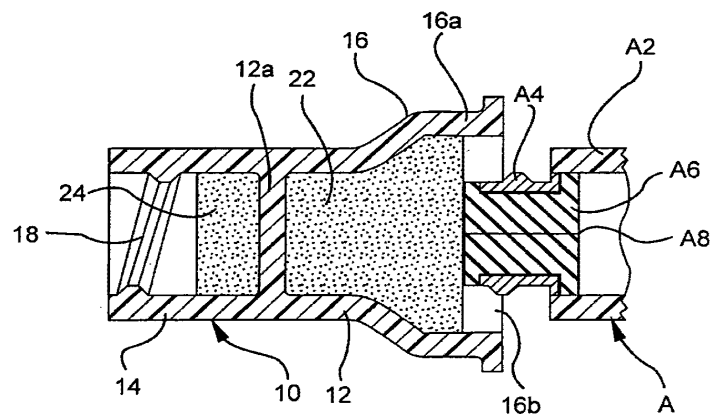


FIG. 5

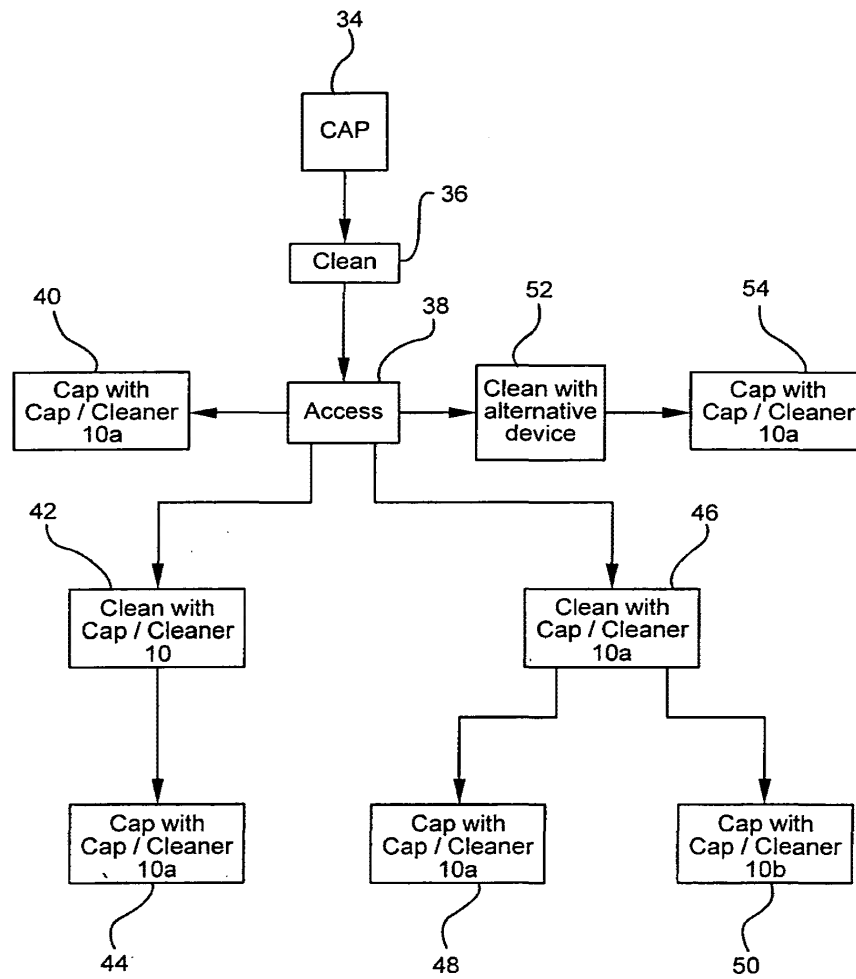


FIG. 6

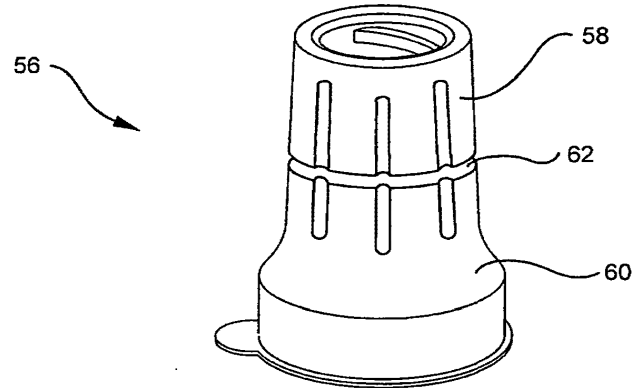
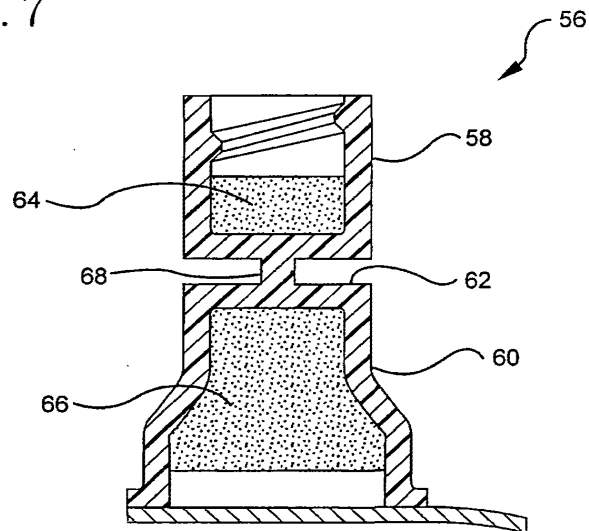


FIG. 7



6/7

FIG. 8

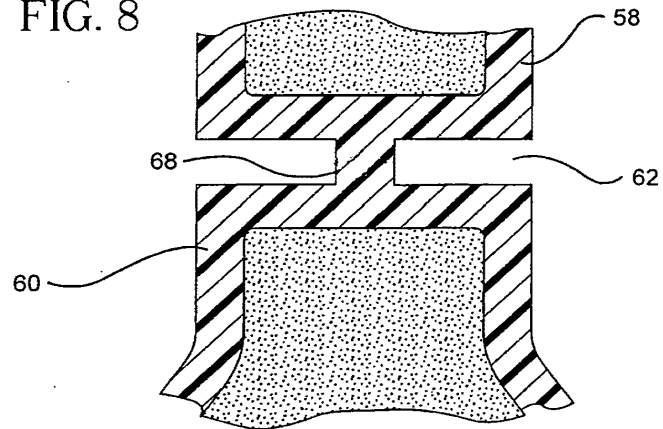


FIG. 9

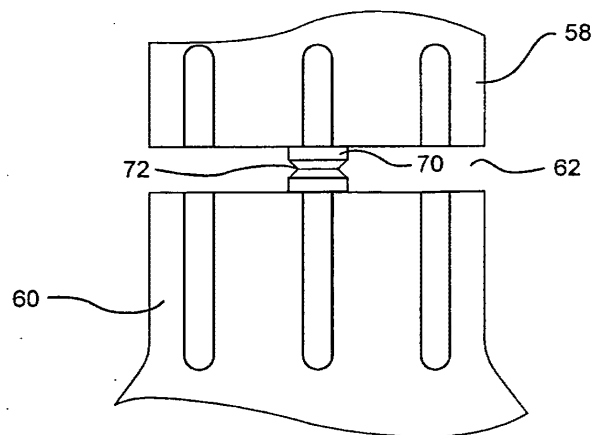


FIG. 10A

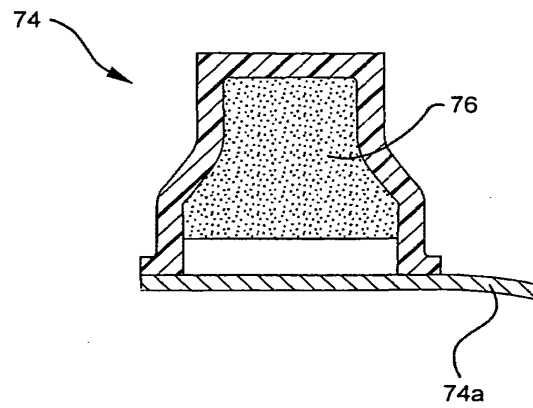
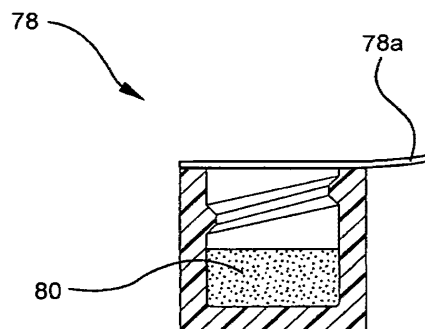


FIG. 10B



DECLARATION FOR UTILITY PATENT APPLICATION (37 C.F.R. 1.63)		Attorney Docket No.	B819.12-0004
		First Named Inventor	Minh Quang Hoang
		COMPLETE IF KNOWN	
☒ Declaration Submitted with Initial Filing	☐ Declaration Submitted after Initial Filing (Surcharge (37 C.F.R. 1.16(e)) Required)	Application Number	
		Filing Date	Herewith
		Group Art Unit	
		Examiner Name	

As a below named inventor, I hereby declare that my residence, post office address, and citizenship are as stated below.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

the specification of which:

☒ is attached hereto OR

☐ was filed on ___ as United States Application Number ___ or PCT International Application Number ___ and was amended on ___ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

DIRECT ALL CORRESPONDENCE TO:

Customer Number	
Attention	David R. Fairbairn
Telephone	(612) 339-1863
Fax	(612) 339-6580

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; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Sole or First Inventor:	
Given Name (First and middle (if any))	Family Name or Surname
Minh Quang	Hoang
Inventor's signature	<i>Minh Quang Hoang</i> Date: 11/16/05
Residence	Sandy, UT Citizenship: USA
Mailing Address	7954 English Oaks Cove
City, State, Country	Sandy, UT, 84093 USA

Second Inventor:	
Given Name (First and middle (if any))	Family Name or Surname
Jonathan Karl	Burkholz
Inventor's signature	<i>Jonathan Karl Burkholz</i> Date: 11/16/2005
Residence	Salt Lake City, UT Citizenship: USA
Mailing Address	1926 East Moor Mont Drive
City, State, Country	Salt Lake City, UT 84117 USA

PATENT APPLICATION SERIAL NO _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

11/22/2005 FFANAI2 00000013 11281711

01 FC:1011	300.00 OP
02 FC:1111	500.00 OP
03 FC:1311	200.00 OP
04 FC:1202	100.00 OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 499-367/88003

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number

11281711

APPLICATION AS FILED - PART I

(Column 1)

(Column 2)

SMALL ENTITY

OR

OTHER THAN
SMALL ENTITY

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	2
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	0
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))		

RATE (\$)	FEE (\$)
N/A	150.00
N/A	\$250
N/A	\$100
X\$ 25 =	
X100 =	
+180=	
TOTAL	

RATE (\$)	FEE (\$)
N/A	300.00
N/A	\$500
N/A	\$200
X\$50 =	100
X200 =	
+360=	
TOTAL	1100

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

(Column 1)

(Column 2)

(Column 3)

SMALL ENTITY

OR

OTHER THAN
SMALL ENTITY

AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))				

RATE (\$)	ADDI- TIONAL FEE (\$)
X\$ 25 =	
X100 =	
+180=	
TOTAL ADD'L FEE	

RATE (\$)	ADDI- TIONAL FEE (\$)
X\$50 =	
X200 =	
+360=	
TOTAL ADD'L FEE	

AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))				

RATE (\$)	ADDI- TIONAL FEE (\$)
X\$ 25 =	
X100 =	
+180=	
TOTAL ADD'L FEE	

RATE (\$)	ADDI- TIONAL FEE (\$)
X\$50 =	
X200 =	
+360=	
TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Inventor Information

Inventor One Given Name:: Minh Quang
Family Name:: Hoang
Name Suffix::
Postal Address Line One:: 7954 English Oaks Cove
Postal Address Line Two::
City:: Sandy
State or Province:: UT
Country::
Postal or Zip Code:: 84093

Inventor Two Given Name:: Jonathan Karl
Family Name:: Burkholz
Name Suffix::
Postal Address Line One:: 1926 East Moor Mont Drive
Postal Address Line Two::
City:: Salt Lake City
State or Province:: UT
Country::
Postal or Zip Code:: 84117

Correspondence Information

Correspondence Customer Number:: 00164
Telephone:: 612/339-1863
Fax:: 612/339-6580
Electronic Mail:: drfairbairn@kinney.com

Application Information

Title Line One:: Patient Fluid Line Access Valve
Title Line Two:: Antimicrobial Cap/Cleaner
Total Drawing Sheets:: 7
Formal Drawings?:: Yes
Application Type:: Utility
Docket Number:: B819.12-0004
Licensed US Govt. Agency::
Contract or Grant Numbers::
Secrecy Order in Parent Application?:: No

Representative Information

Representative Customer Number:: 00164

Continuity Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::

Foreign Priority Information

Country::	Application No.::	Filing Date::	Priority Claimed::

Assignee Information

Name::	Becton, Dickinson and Company
Address line one::	1 Becton Drive
Address line two::	
City::	Franklin Lakes
State or Province::	NJ
Postal or zip code::	07417



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KINNEY & LANGE

A PROFESSIONAL ASSOCIATION

THE KINNEY & LANGE BUILDING
312 SOUTH THIRD STREET
MINNEAPOLIS, MINNESOTA 55415-1002

INFO@KINNEY.COM
FACSIMILE (612) 339-6580
TELEPHONE (612) 339-1863

CATHERINE J. BENSON
(612) 337-9373
cjbenson@kinney.com

January 19, 2006

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application of Minh Quang Hoang
Appln. No. : 11/281,711
Filed : November 17, 2005
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Our File No. : B819.12-0004

Dear Sir:

Enclosed for filing are the following papers in connection with the above-identified patent application:

1. Power of Attorney; and
2. Submission Under 37 C.F.R. 3.73(b) with photocopy of Assignment attached.

Respectfully submitted,

KINNEY & LANGE, P.A.

Catherine J. Benson

CJB:hlw
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor : Minh Quang Hoang

Appln. No. : 11/281,711

Filed : November 17, 2005

Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER

Docket No. : B819.12-0004

Group Art Unit: 3763

Examiner:

SUBMISSION UNDER 37 C.F.R. 3.73(b)

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Becton, Dickinson and Company, a New Jersey company, is an owner of the patent application identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel __, Frame __, or a copy of which is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or a copy of which is attached.
2. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or a copy of which is attached.

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The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or a copy of
which is attached.

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature: 
David W. Highet

Date: 1/16/06

Title: Assistant Secretary

ASSIGNMENT

Attorney Docket No.

B819.12-0004

First Named Inventor : Minh Quang Hoang

Title : PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

WHEREAS, I, Minh Quang Hoang, of Sandy, UT, USA, and Jonathan Karl Burkholz, of Salt Lake City, UT, USA, have invented certain new and useful improvements as described in an application entitled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER for Letters Patent of the United States, the application having been executed on even date herewith, and/or being identifiable in the United States Patent and Trademark Office by Application No. _____, filed _____; and

WHEREAS, Becton, Dickinson and Company, a corporation organized and existing under the laws of the State of New Jersey, and having offices at 1 Becton Drive, Franklin Lakes, NJ 07417, ("Assignee") is desirous of acquiring the entire right, title and interest in and to the invention, the application, and any and all Letters Patent or similar legal protection, foreign or domestic, to be obtained therefor;

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, I transfer to Assignee, its successors and assigns, my entire right, title and interest in and to the invention, the above-identified application, corresponding domestic and foreign applications, all Letters Patent or similar legal protection issuing thereon, and all rights and benefits under any applicable treaty or convention; and I authorize the Commissioner of Patents and Trademarks of the United States or foreign equivalent thereof to issue the Letters Patent or similar legal protection to the Assignee.

I authorize the Assignee, its successors and assigns, to insert in this instrument the filing date and application number of the application when ascertained.

I authorize the Assignee, its successors and assigns, or anyone it may properly designate, to apply for Letters Patent or similar legal protection, in its own name if desired, in any and all foreign countries.

I represent to the Assignee, its successors and assigns, that I have not and shall not execute any writing or do any act whatsoever conflicting with this Assignment. I, my executors or administrators, will at any time upon request, without additional consideration, but at the expense of the Assignee, its successors and assigns, execute such additional writings and do such additional acts as the Assignee, its successors and assigns, may deem desirable to perfect its enjoyment of this grant, and render all assistance in making application for and obtaining, maintaining, and enforcing the Letters Patent or similar legal protection on the invention in any and all countries.

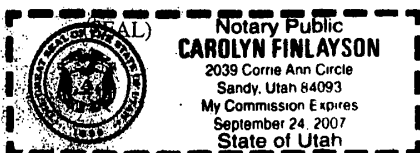
Minh Quang Hoang 10
Minh Quang Hoang

STATE OF Utah

COUNTY OF Salt Lake

Subscribed and sworn to before me, a Notary Public, this ____ day of _____, 2005.

Carolyn Finlayson
Notary Public



BEST AVAILABLE COPY

ASSIGNMENT

Attorney Docket No.

B819.12-0004

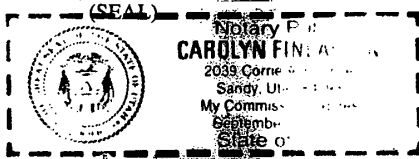
Jonathan Karl Burkholz
Jonathan Karl Burkholz

STATE OF Utah

COUNTY OF Salt Lake

Subscribed and sworn to before me, a Notary Public, this 16 day of November, 2005.

Carolyn Finlayson
Notary Public

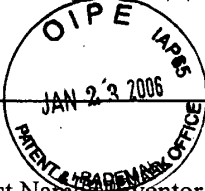


BEST AVAILABLE COPY

POWER OF ATTORNEY

Attorney Docket No. *IRJ*

B819.12-0004



First Named Inventor : Minh Quang Hoang

Title : PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

In the patent application:

☐ identified above (and submitted to the Patent and Trademark Office herewith).

☒ filed on November 17, 2005 as Application No. 11/281,711.

I appoint the attorneys and agents associated with Customer Number 58233 to prosecute the patent application identified above and to transact all business in the Patent and Trademark Office connected therewith, including full power of association, substitution and revocation.

I ratify all prior actions taken by Kinney & Lange, P.A. or the attorneys and agents mentioned above in connection with the prosecution of the above-mentioned patent application.

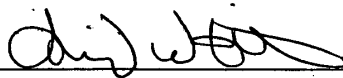
I authorize Kinney & Lange, P.A. to mark the appropriate space above and to insert the filing date and application number of the application, as appropriate.

I authorize the attorneys and agents named herein to accept and follow instructions from as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the attorneys and agents and the undersigned. In the event of a change in the persons from whom instructions may be taken, the attorneys and agents named herein will be so notified by the undersigned.

Please address all correspondence and telephone calls to Customer Number 58233, attention Catherine J. Benson, Telephone (612) 339-1863, Fax (612) 339-6580.

BECTON, DICKINSON AND COMPANY

Signature:


David W. Highet

Dated:

1/16/06

Title:

Assistant Secretary



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KINNEY & LANGE

A PROFESSIONAL ASSOCIATION

THE KINNEY & LANGE BUILDING
312 SOUTH THIRD STREET
MINNEAPOLIS, MINNESOTA 55415-1002

INFO@KINNEY.COM
FACSIMILE (612) 339-6580
TELEPHONE (612) 339-1863

DAVID R. FAIRBAIRN
(612) 337-9357
drfairbairn@kinney.com

May 10, 2007

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application of Minh Quang Hoang
Appln. No. : 11/281,711
Filed : November 17, 2005
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Atty Docket : P-6836
Our File No. : B819.12-0004

Dear Sir:

Enclosed for filing are the following papers in connection with the above-identified patent application:

1. Power of Attorney; and
2. Return Receipt Postcard.

Respectfully submitted,

KINNEY & LANGE, P.A.


David R. Fairbairn

DRF:dlo
Enclosures



POWER OF ATTORNEY

Attorney Docket No.

P-6836

First Named Inventor : Minh Quang Hoang

Title : PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

In the patent application:

— identified above (and submitted to the Patent and Trademark Office herewith).

X filed on November 17, 2005 as Application No. 11/281,711.

I appoint the attorneys and agents associated with Customer Number 58233 to prosecute the patent application identified above and to transact all business in the Patent and Trademark Office connected therewith, including full power of association, substitution and revocation.

I ratify all prior actions taken by Kinney & Lange, P.A. or the attorneys and agents mentioned above in connection with the prosecution of the above-mentioned patent application.

I authorize Kinney & Lange, P.A. to mark the appropriate space above and to insert the filing date and application number of the application, as appropriate.

Please address all correspondence and telephone calls to Customer Number 58233, attention Mony R. Ghose, Telephone (201) 847-6802, Fax (201) 848-9228.

BECTON, DICKINSON AND COMPANY

Signature:

David W. Highet

Dated: JAN. 8, 2007

Title:

Vice President and Chief IP Counsel



PATENT, TRADEMARK,
COPYRIGHT, AND RELATED
INTELLECTUAL PROPERTY LAW

KINNEY & LANGE

A PROFESSIONAL ASSOCIATION

THE KINNEY & LANGE BUILDING
312 SOUTH THIRD STREET
MINNEAPOLIS, MINNESOTA 55415-1002

INFO@KINNEY.COM
FACSIMILE (612) 339-6580
TELEPHONE (612) 339-1863

DAVID R. FAIRBAIRN
(612) 337-9357
drfairbairn@kinney.com

May 10, 2007

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application of Minh Quang Hoang
Appln. No. : 11/281,711
Filed : November 17, 2005
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Atty. Docket : P-6836
Our File No. : B819.12-0004

Dear Sir:

Enclosed for filing are the following papers in connection with the above-identified patent application:

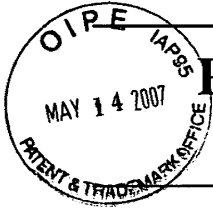
1. Power of Attorney; and
2. Return Receipt Postcard.

Respectfully submitted,

KINNEY & LANGE, P.A.


David R. Fairbairn

DRF:dlo
Enclosures



POWER OF ATTORNEY

Attorney Docket No.

P-6836

First Named Inventor : Minh Quang Hoang

Title : PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

In the patent application:

— identified above (and submitted to the Patent and Trademark Office herewith).

X filed on November 17, 2005 as Application No. 11/281,711.

I appoint the attorneys and agents associated with Customer Number 58233 to prosecute the patent application identified above and to transact all business in the Patent and Trademark Office connected therewith, including full power of association, substitution and revocation.

I ratify all prior actions taken by Kinney & Lange, P.A. or the attorneys and agents mentioned above in connection with the prosecution of the above-mentioned patent application.

I authorize Kinney & Lange, P.A. to mark the appropriate space above and to insert the filing date and application number of the application, as appropriate.

Please address all correspondence and telephone calls to Customer Number 58233, attention Mony R. Ghose, Telephone (201) 847-6802, Fax (201) 848-9228.

BECTON, DICKINSON AND COMPANY

Signature:

David W. Highet

Dated: JAN. 8, 2007

Title:

Vice President and Chief IP Counsel



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/281,711	11/17/2005	Minh Quang Hoang	B819.12-0004

CONFIRMATION NO. 9168

58233
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC110
FRANKLIN LAKES, NJ07417-1880

Title: Patient fluid line access valve antimicrobial cap/cleaner

Publication No. US-2007-0112333-A1

Publication Date: 05/17/2007

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 703-305-3028.

Pre-Grant Publication Division, 703-605-4283



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	B819.12-0004	9168
58233 7590 07/29/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kinney & Lange) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 07/29/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 14 May 2007.

2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a device for antiseptically maintaining a patient fluid line access valve comprising housing and a pad within the housing for reducing the amount of microbes on an access portion, classified in class 604, subclass 533.
 - II. Claims 11-22, drawn to an apparatus and method of reducing the risk of contamination of a patient fluid line access valve comprising means for cleaning an access portion of an access valve with a cleaning solution, classified in class 604, subclass 265.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because invention I does not require a cleaning solution. The subcombination has separate utility such as using a pad to minimize the amount of microbes on an access portion.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

2. This application contains claims directed to the following patentably distinct Species I: Figs 1-5; Species II: 6-10B. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: Minh Quang Hoang	
Appln. No.	: 11/281,711	Confirmation No.: 9168
Filed	: November 17, 2005	Group Art Unit: 3767
Title	: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	Examiner: Andrew M. Gilbert
Docket No.	: B819.12-0004	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FILED VIA EFS-WEB

Dear Sir:

This is in response to the Office Action mailed on July 29, 2009, in which a restriction was required between Invention I (claims 1-10) and Invention II (claims 11-22). Applicant elects Invention I (claims 1-10) for prosecution, without traverse.

The Office Action also included a requirement that Applicant elected either Species I (FIGS. 1-5) or Species II (FIGS 6-10B). Applicant elects Species II without traverse. Claims 1-10 read on Species II, and are generic to both Species I and Species II.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: August 24, 2009

By: /David R. Fairbairn/
David R. Fairbairn, Reg. No. 26,047
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

DRF:ks

Electronic Acknowledgement Receipt	
EFS ID:	5936538
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	58233
Filer:	David Richard Fairbairn
Filer Authorized By:	
Attorney Docket Number:	P-6836
Receipt Date:	24-AUG-2009
Filing Date:	17-NOV-2005
Time Stamp:	14:48:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	2009-8-24- RestrictionRequirement-P6836- B819-12-0004.pdf	17381 fa04d0be0dd6884578fd0122c790b4ab221 dd2c1	no	1
Warnings:					
Information:					

Total Files Size (in bytes):	17381
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

PLUS Search Results for S/N 11281711, Searched Fri Nov 20 14:06:22 EST 2009
The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

5531341	82	5267968	62
4326569	81		
5203771	81		
20070112333	81		
20070176117	81		
6027492	63		
4375849	63		
4867309	63		
5913631	63		
6245056	63		
20030233074	63		
5401239	62		
5505695	62		
6206854	62		
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4324516	62		
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4392326	62		
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4417888	62		
4453636	62		
4465200	62		
4484595	62		
4496349	62		
4503560	62		
4513888	62		
4537273	62		
4538564	62		
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4801029	62		
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5202849	62		
5218736	62		



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
58233 7590 11/25/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kinney & Lange) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 11/25/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I: Claims 1-10 and Species II: Figs 6-10b in the reply filed on 8/24/2009 is acknowledged.
2. Claims 11-20 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/24/2009.
3. Thus, claims 1-10 are pending for examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites both a dry pad and wet pad; however, the claims appear to only be claiming one cavity for housing a pad, not two pads. It is unclear that the applicant has recited two cavities for housing each of the dry and wet pads. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Genatempto et al (4440207). Genatempto et al discloses a device for antiseptically maintaining a patient fluid line access valve, the device comprising: a housing (10) for covering an access portion of the access valve; and a pad (24) within the housing for contacting an access portion of the access valve to reduce the amount of microbes on the access portion; a cap with a cavity (28) for covering the access portion; wherein the pad is within the cavity of the cap (Figs 1-3); wherein the pad is impregnated with an antimicrobial agent (col 3, Ins 1-8, 40-57); wherein the cap includes a thread (38) within the cavity; wherein the pad is one of a dry pad and a wet pad (col 3, Ins 1-8, 40-57); wet pad contains a cleaning solution (col 3, Ins 1-8, 40-57); wherein the housing further comprises: a hood with a chamber (28) for covering the access portion; a lid (20) sealing the pad within the housing.

8. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Menyhay (5554135). Menyhay discloses a device for antiseptically maintaining a patient fluid line access valve, the device comprising: a housing (10) for covering an access portion of the access valve; and a pad (12) within the housing for contacting an access portion of the access valve to reduce the amount of microbes on the access portion; a cap with a cavity (Fig 1) for covering the access portion; wherein the pad is within the cavity of the cap (Fig 3); wherein the pad is impregnated with an antimicrobial agent (12; col 6, Ins 44-67); wherein the cap includes a thread (15) within the cavity; wherein the pad is one of a dry pad and a wet pad (col 6, Ins 44-67); wet pad contains a cleaning solution (held in capsule 11); wherein the housing further comprises: a hood

with a chamber (Fig 1; annular walls 10) for covering the access portion; a lid (14) sealing the pad within the housing.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 3767

Page 5

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/281,711		Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW M. GILBERT		Art Unit 3767	Page 1 of 1

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*	B	US-4,432,764 A	02-1984	Lopez, Georges	604/533
*	C	US-4,440,207 A	04-1984	Genatempo et al.	150/154
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*	G	US-5,554,135 A	09-1996	Menyhay, Steve Z.	604/256
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*	M	US-2009/0149819 A1	06-2009	Chelak, Todd M.	604/246

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	56	((MINH) near2 (HOANG)). INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:29
L2	16	((JONATHAN) near2 (BURKHOLZ)). INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:30
L3	2	"US 20070112333"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2009/11/20 13:30
L4	0	("2007/0112333").URPN.	USPAT	OR	ON	2009/11/20 13:30
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L6	9	("20060024372" "5763412" "6617294" "6299610" "6350251" "6482197" "6592564" "6679870" "6685694"). PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:51
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L8	766	(604/265).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
L9	124	(604/267).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
L10	237	(7 8 9) and (antiseptic\$4 clean\$4 antimicrobial antibacterial) and valve	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:54
L11	107	10 and connector	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
L12	16	10 and pad	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55

L13	32	("20020066702" "20020091424" "20020123787" "20020193752" "20040116845" "20050038376" "20050038376" "20050095351" "20050256500" "4765588" "5251873" "5260020" "5295657" "5295658" "5312813" "5342316" "5441487" "5474544" "5501426" "5533708" "5549651" "5957898" "6171287" "6261282" "6282444" "6344033" "6428491" "6562295" "6595964" "6651956" "6669681" "6866656" "6908459"). PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:01
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L18	62	(13 15 16 17) and (antiseptic\$4 clean\$4 antimicrobial antibacterial steriliz\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:11
L19	13	((("4354490") or ("4432764") or ("4440207") or ("4655762") or ("4778447") or ("5554135") or ("5334388") or ("5792120") or ("6045539") or ("20070202177") or ("20080027399") or ("20080177250") or ("20090149819"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 14:27

EAST Search History (I nterference)

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11/ 20/ 2009 3:11:21 PM**C:\ Documents and Settings\ agilbert\ My Documents\ EAST\ Workspaces\ 11281711.wsp**



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BIB DATA SHEET

CONFIRMATION NO. 9168

SERIAL NUMBER 11/281,711	FILING or 371(c) DATE 11/17/2005 RULE	CLASS 604	GROUP ART UNIT 3767	ATTORNEY DOCKET NO. P-6836	
APPLICANTS Minh Quang Hoang, Sandy, UT; Jonathan Karl Burkholz, Salt Lake City, UT; ** CONTINUING DATA ***** ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 12/20/2005					
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and <u>/ANDREW M GILBERT/</u> Acknowledged <u>Examiner's Signature</u>	☐ Met after Allowance <u>Initials</u>	STATE OR COUNTRY UT	SHEETS DRAWINGS 7	TOTAL CLAIMS 22	INDEPENDENT CLAIMS 3
ADDRESS David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kinney & Lange) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880 UNITED STATES					
TITLE Patient fluid line access valve antimicrobial cap/cleaner					
FILING FEE RECEIVED 1100	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees			
		☐ 1.16 Fees (Filing)			
		☐ 1.17 Fees (Processing Ext. of time)			
		☐ 1.18 Fees (Issue)			
		☐ Other _____			
		☐ Credit			

Index of Claims 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant											☐ CPA	☐ T.D.	☐ R.1.47
CLAIM		DATE											
Final	Original	11/20/2009											
	1	✓											
	2	✓											
	3	✓											
	4	✓											
	5	✓											
	6	✓											
	7	✓											
	8	✓											
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	10	✓											
	11	N											
	12	N											
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	14	N											
	15	N											
	16	N											
	17	N											
	18	N											
	19	N											
	20	N											

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

SEARCHED			
Class	Subclass	Date	Examiner
604	533, 265, 267	11/20/2009	AG

SEARCH NOTES			
Search Notes	Date	Examiner	
Searched EAST class/subclass and keyword search - see attached sheets	11/20/2009	AG	
Inventor Name and PLUS search	11/20/2009	AG	
Forward/Backward citation searches	11/20/2009	AG	

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW M GILBERT/ Examiner.Art Unit 3767	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: Minh Quang Hoang	
Appln. No.	: 11/281,711	Confirmation No.: 9168
Filed	: November 17, 2005	Group Art Unit: 3767
Title	: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	Examiner: Andrew M. Gilbert
Docket No.	: B819.12-0004 P-6836	

AMENDMENT

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FILED VIA EFS-WEB

INTRODUCTION

This is in response to the Office Action mailed on November 25, 2009. Please amend the above-identified application as follows:

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 4, 6, 8, and 9, cancel claims 2, 3, 5, 7, 10-22, and add new claims 23-44 such that the status of the claims is as follows:

1. (Currently amended) A device for ~~antiseptically~~ maintaining a patient fluid line access valve having an access portion with an end face that includes a septum, the device comprising:

a housing for covering [[an]] the access portion of the access valve, the housing having an open end, a closed end, and a cavity; [[and]]

a wet pad containing a cleaning solution positioned within the cavity housing for contacting the end face of the [[an]] access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity so that the end face of the access portion contacts the wet pad.

2. (Canceled)

3. (Canceled)

4. (Currently amended) The device of claim [[2]] 1 wherein the [[cap]] housing includes a thread within the cavity for engaging an external thread on the access valve.

5. (Canceled)

6. (Currently amended) The device of claim [[5]] 1 wherein the wet pad contains [[a]] an alcohol-based cleaning solution.

7. (Canceled)

8. (Currently amended) The device of claim [[7]] 6 wherein the ~~wet pad contains~~ a cleaning solution contains about 50% to about 100% of an alcohol solution.

9. (Currently amended) The device of claim [[8]] 1 wherein the wet pad contains an antimicrobial agent.

10-22. (Canceled)

23. (New) The device of claim 9, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

24. (New) The device of claim 1, wherein the wet pad contains a water-based cleaning solution.

25. (New) The device of claim 1, wherein the housing is formed of a polyethylene or polypropylene material.

26. (New) The device of claim 1, wherein the wet pad comprises a sponge formed of a polyester material, and wherein the cleaning solution includes alcohol.

27. (New) A device for antiseptically maintaining a patient fluid line access valve, the device comprising:

a cap with a single cavity for covering an access portion of the access valve, the access portion including an exposed surface of a septum of the access valve

and at least a portion of an exposed surface of a housing of the access valve that surrounds the septum;

a wet pad within the single cavity and containing a cleaning solution, the wet pad for contacting the access portion of the access valve to apply the cleaning solution to the access portion to reduce the amount of microbes on the access portion; and

a lid for providing a moisture barrier over the wet pad, the lid being removable to allow the cap to be placed over the access portion of the access valve with the wet pad in contact with the access portion.

28. (New) The device of claim 27, wherein the pad is impregnated with an antimicrobial agent.

29. (New) The device of claim 27, wherein the wet pad contains an alcohol-based cleaning solution.

30. (New) The device of claim 29, wherein the cleaning solution contains about 50% to about 100% of an alcohol solution.

31. (New) The device of claim 27, wherein the wet pad contains an antimicrobial agent.

32. (New) The device of claim 31, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

33. (New) The device of claim 27, wherein the wet pad contains a water-based cleaning solution.

34. (New) The device of claim 27, wherein the cap is formed of a polyethylene or polypropylene material.

35. (New) The device of claim 27, wherein the wet pad comprises a sponge formed of a polyester material, and wherein the cleaning solution includes alcohol.
36. (New) A device for maintaining a patient fluid line access valve, the device comprising:
a housing for covering an end face of the access valve;
a wet pad within the housing and containing a cleaning solution, the wet pad for contacting the end face of the access valve to reduce the amount of microbes on the access valve; and
a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the end face of the access valve to be inserted into the housing and contact the wet pad.
37. (New) The device of claim 36, wherein the housing includes a thread within the cavity for engaging an external thread on the access valve.
38. (New) The device of claim 36, wherein the wet pad contains an alcohol-based cleaning solution.
39. (New) The device of claim 38, wherein the cleaning solution contains about 50% to about 100% of an alcohol solution.
40. (New) The device of claim 36, wherein the wet pad contains an antimicrobial agent.
41. (New) The device of claim 40, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

42. (New) The device of claim 36, wherein the wet pad contains a water-based cleaning solution.

43. (New) The device of claim 36, wherein the housing is formed of a polyethylene or polypropylene material.

44. (New) The device of claim 36, wherein the wet pad comprises a sponge formed of a polyester material, and wherein the cleaning solution includes alcohol.

REMARKS

This Amendment is in response to the Office Action mailed November 25, 2009, in which claims 1-10 were rejected and claims 11-20 were withdrawn from consideration. With this Amendment, claims 1, 4, 6, 8, and 9 have been amended, claims 2, 3, 5, 7, and 10-22 are cancelled, and claims 23-44 are added. Claims 1, 4, 6, 8, 9, and 23-44 are presented for reconsideration and allowance.

In the Office Action, claim 5 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. With the cancellation of claim 5, the rejection has been rendered moot.

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Genatempo et al. (U.S. Patent No. 4,440,207). With this Amendment, independent claim 1 has been amended to more specifically define the device of the present invention, which is used to maintain a patient fluid line access valve of the type that has an access portion with an end face that includes a septum. These types of access valves are sometimes referred to as needleless valves or split septum valves, and were developed to address concerns relating to needle stick injuries that could result in transmission of serious diseases such as HIV virus or hepatitis.

With the increasing use of needles and hypodermic needles to access IV lines, accidental needle stick injuries generated great concerns about health care professionals and have drawn the attention of practitioners, the healthcare industry, and regulators. As HIV virus cases increased, HIV transmission due to needle stick injuries became quite threatening to healthcare providers. Other serious viruses, such as hepatitis, could also be transmitted through accidental needle sticks. In 1992, the FDA issued an alert to healthcare providers advising of the high rates of needle stick injuries. The alert also reported that incidents have occurred in which hypodermic needles were broken off inside intravenous lines harming the patients. The FDA alert stated, "There is no evidence that patients blood-stream infection have increased with the implementation of needleless systems." The healthcare industry responded positively with new products referred to as Needleless IV Access Systems.

The products included a split septum mounted on one end of the connector device that is attached to an IV line. IV access is accomplished by inserting a blunt plastic cannula through the split in the septum. An example of this type of valve is BD Q-Syte™ valve from Becton, Dickinson Company, the Assignee of the present invention. The BD Q-Syte™ valve is illustrated in FIG. 1 of the present application as access valve A.

Needleless IV access systems also include a lure activated access device. The IV access is accomplished by depressing a plunger in the device with a syringe or IV lined lure. When the plunger is depressed, fluid can flow through the device into the IV line.

The needleless IV access systems have reduced the accidental needle stick injuries preventing transmission of communicable diseases and, to some extent, patient blood-stream infection. However, investigative studies have shown that there are negative outcomes associated with needleless IV systems. A significant increase of blood-stream infections (BSI) have been reported in several studies published in respected scientific journals. The Center for Disease Control and Prevention (CDC) reports over 350,000 hospital acquired infections occur every year. A 2004 study by the state of Pennsylvania reported that hospital stays increased by an average of 23 days and patient's mortality rate increased an average of 18%, and the overall increase cost of care of a patient with acquired blood-stream infection was approximately \$250,000.

Studies of bacterial colonization on needleless valves have found microorganisms present on the split septum as well as the plastic rim of needleless valves. The device of the present invention provides an easy to use device that addresses the formation of microorganisms or bio-films in the vulnerable areas of needleless valves, particularly the septum and the rim surrounding the septum.

The Genatempo patent shows a protective cap that was used in conjunction with a catheter connector – not a needleless IV fluid line access valve. The connector does not have an end face that includes a septum. The protective cap 10 of Genatempo includes an absorbent material 24 mounted on the sidewalls of the upper cavity. The absorbent material 24 contains an antiseptic or antibacterial agent that is used to clean the sidewalls of connector 32 that are located below flange 36 in FIG. 3. The lower end of connector 32 is threaded into a smaller threaded cavity at the lower end

of cap 10. There is no absorbent material located in that smaller cavity, and no cleaning or antiseptic treatment is provided to the end face of connector 32. The protective cap described in Genatempo, therefore, is unsuitable for maintaining a fluid line access valve having an access portion with an end face that includes a septum.

As amended, claim 1 clarifies that the device of the invention is used for maintaining an access valve having an access portion with an end face that includes a septum. Claim 1 has also been amended to more specifically define the structure of the housing, the location and function of the wet pad, and the lid, which provides a moisture barrier. The lid is removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity of the housing so that the end face of the access portion contacts the wet pad. As amended, claim 1 is neither taught nor suggested by Genatempo. The rejection under 35 U.S.C. § 102(b) based upon Genatempo should be withdrawn with respect to independent claim 1 and dependent claims 4, 6, 8, and 9.

Claims 1-10 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Menyhay (U.S. Patent No. 5,554,135). In contrast to Genatempo, Menyhay discloses a device that is intended to be used with a needleless type access valve. The approach Menyhay takes, however, differs from the present invention. Menyhay requires a breakable sealed capsule 11 that contains an antiseptic, bactericidal and virucidal solution. Capsule 11 is mounted near the closed end of cylinder 10, adjacent to a puncturing device 13. Sponge 12 is positioned in front of capsule 11 within the cavity. Sponge 12 is dry before device 10 is used. The solution is maintained within capsule 11. When external junction port 19 is connected to cylinder 10, external threads 17 are threaded into internal threads 15 of cylinder 10. Septum 18 must push against sponge 12 with enough force to cause sponge 12 to press against capsule 11 until it is ruptured by projection 9, as shown in FIG. 3. Only then the solution from capsule 11 reach sponge 12. The antiseptic agents escape from capsule 11 and flow around capsule 11 to reach sponge 12 (Menyhay col. 6, line 59 – col. 7, line 3).

The Menyhay device is much more complicated then the device of the present invention. It requires a special antiseptic reservoir (capsule 11) that must be filled and sealed and inserted into cylinder 10 before the sponge 12 is inserted. It also requires that cylinder 10 have a projection 9 to puncture or rupture capsule 11. Menyhay also requires annular O-ring 14 at or near

the open end of cylinder 10. O-ring 14 is required to create a seal over the end of the port while the device is being screwed onto the end of port 19.

The presence of projection 9 needed to rupture capsule 11 raises the danger that during the compression of sponge 12 and capsule 11, projection 9 or capsule 11 could deform in such a way that the surface of the septum is damaged. This could potentially cause a needleless valve malfunction. Projection 9 used by Menyhay also may result in uneven pressure between sponge 12 and the end surface of the septum, which could compromise the delivery of antimicrobial material to the septum surface, including the internal surfaces of the septum.

As amended, claim 1 is neither taught nor suggested by Menyhay. It requires a wet pad, rather than a dry pad, rupturable capsule, and projection as described by Menyhay.

In addition, amended claim 1 requires a lid over the opened end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier. This prevents evaporation of the cleaning solution from the wet pad prior to use. In Menyhay, a lid is not provided.

The device of the present invention, as defined in independent claim 1 and dependent claims 4, 6, 8, and 9, is simpler in construction than Menyhay, and is reliable and effective in delivering cleaning solution to the end face of the access portion of the access valve. The rejection of claims 1, 4, 6, 8, and 9 based upon Menyhay should be withdrawn.

With this Amendment, claims 23-44 have been added. Claims 23-26 are dependent claims. Claim 23 depends from claim 9, while claims 24-26 depend directly from independent claim 1. Claims 23-26 are also allowable over both Genatempo and Menyhay.

Independent claim 27 and dependent claims 28-35, and independent claim 36 and dependent claims 37-44 also define a device that is not taught or suggested by either Genatempo or Menyhay. Claims 27-44 are also in condition for allowance.

In conclusion, with the amendments to claims 1, 4, 6, 8, and 9 and the addition of claims 23-44, this application is now in condition for allowance. Notice to that effect is respectfully requested.

First Named Inventor: Minh Quang Hoang

Application No.: 11/281,711

-11-

The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.16 and 1.17, or credit any overpayment, to Deposit Account No. 11-0982.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: February 19, 2010

By: /David R. Fairbairn/
David R. Fairbairn, Reg. No. 26,047
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

DRF:ks

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		David Richard Fairbairn		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	5	52	260
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				260

Electronic Acknowledgement Receipt	
EFS ID:	7047045
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	58233
Filer:	David Richard Fairbairn
Filer Authorized By:	
Attorney Docket Number:	P-6836
Receipt Date:	19-FEB-2010
Filing Date:	17-NOV-2005
Time Stamp:	15:42:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$260
RAM confirmation Number	2184
Deposit Account	110982
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2010-2-19-Amendment-B819-12-0004-P-6836.pdf	49949 3392d8928ae23395a599eeca1052a76f421f9bb	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Amendment Copy Claims/Response to Suggested Claims		2	6	
	Applicant Arguments/Remarks Made in an Amendment		7	11	
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29966 bd06a67740ad4e095b23d8ac12df4d3f7dd3dbda	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			79915		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed		
APPLICATION AS FILED – PART I											
(Column 1)			(Column 2)		SMALL ENTITY ☐		OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)			RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A				N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A				N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A				N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	OR		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.											
TOTAL					TOTAL						
APPLICATION AS AMENDED – PART II											
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	02/19/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 27	Minus	** 22	=	5	X \$	=	OR	X \$52=	260
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	=	0	X \$	=	OR	X \$220=	0
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE	260	
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=			X \$	=		
	Independent (37 CFR 1.16(h))	*	Minus	***	=			X \$	=		
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

Legal Instrument Examiner:
/THERESA I. OKON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed		
APPLICATION AS FILED – PART I											
(Column 1)			(Column 2)		SMALL ENTITY ☐		OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)			RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A				N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A				N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A				N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	OR		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.											
			TOTAL				TOTAL				
APPLICATION AS AMENDED – PART II											
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	02/19/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 27	Minus	** 22	=	5	X \$	=	OR	X \$52=	260
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	=	0	X \$	=	OR	X \$220=	0
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	260	
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR	X \$	=	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR	X \$	=	
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.											
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".											
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Legal Instrument Examiner:
/THERESA I. OKON/



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
58233 7590 06/11/2010 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kinney & Lange) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 06/11/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 19 February 2010.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,4,6,8,9 and 23-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,4,6,8,9 and 23-44 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 17 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. The applicant amended claims 1, 4, 6, 8, and 9; claims 2, 3, 5, 7, 10-22 were cancelled; and new claims 23-44 were added.
2. Thus, claims 1, 4, 6, 8, 9, 23-44 are pending for examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, 9, 27, 28, 31, 36, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (5242425) in view of Lake, Jr. et al (20040258560). White et al discloses a device for maintaining a patient fluid line access (18; Fig 1) having an access portion with an end face that includes a septum (54); the device comprising: a housing (66), having an open end (64), a closed end (Fig 1) and a cavity (e.g. area housing 68; Fig 4), a wet pad (68) containing a cleaning solution (Summary; col 3, Ins 36-40; col 6, Ins 52-58) for contacting the end face of the access portion of the access valve (Summary); a thread within the cavity for engaging an external thread on the access valve (76; Fig 7); the wet pad containing an antimicrobial agent (Summary; col 3, Ins 36-40; col 6, Ins 52-58);
5. However, White et al does not appear to disclose a removable lid over the open end of the housing to seal the cavity with the wet pad to provide a moisture barrier.

Lake, Jr. et al teaches that it is known to have a removable lid over the open end of the housing to seal the cavity with the wet pad to provide a moisture barrier (30) for the purpose of maintaining the sterility of the device prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by White et al with the lid as taught by Lake, Jr. et al for the purpose of maintaining the sterility of the device prior to use.

6. Claims 6, 8, 23-24, 29-30, 32, 33, 38, 39, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Lake Jr et al. White et al and Lake Jr et al discloses the invention substantially as claimed except for expressly disclosing the wet pad containing an alcohol based cleaning solution, about 50-100% of an alcohol based cleaning solution, chlorexidine gluconate or chlorhexidine diacetate, or a water based cleaning solution. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the wet pad containing an alcohol based cleaning solution, about 50-100% of an alcohol based cleaning solution, chlorexidine gluconate or chlorhexidine diacetate, or a water based cleaning solution because the Applicant has not disclosed that having provides an advantage, is used for a particular purpose, or solves a stated problem.

Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the cleaning solution of White et al in view of Jake et al because it performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify

White et al in view of Jake Jr et al to obtain the invention as specified in claims 6, 8, 23-24, 29-30, 32, 33, 38, 39, 41-42.

7. Claim 25, 34, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Jake Jr et al. White et al in view of Jake Jr et al discloses the invention substantially as claimed except for expressly disclosing the housing being formed of a polyethylene or polypropylene material. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the housing being formed of a polyethylene or polypropylene material because the Applicant has not disclosed that having the housing being formed of a polyethylene or polypropylene material provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the housing material of White et al in view of Jake Jr et al because it performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify White et al in view of Jake Jr et al to obtain the invention as specified in claims 25, 34, and 43.

8. Claim 26, 35, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Jake Jr et al. White et al in view of Jake Jr et al discloses the invention substantially as claimed except for expressly disclosing the sponge being a polyester material. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the sponge being a polyester material because the Applicant has not disclosed that having the sponge

being a polyester material provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the sponge of White et al in view of Jake Jr et al because it performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify White et al in view of Jake Jr et al to obtain the invention as specified in claims 26, 35, 44.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 Form.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

Application/Control Number: 11/281,711

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Art Unit: 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/281,711		Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW M. GILBERT		Art Unit 3767	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2,961,682 A	11-1960	GABRIELE WURMBOCK et al.	15/104.94
*	B	US-4,282,891 A	08-1981	Duceppe, Antoine	132/73.5
*	C	US-4,432,764 A	02-1984	Lopez, Georges	604/533
*	D	US-4,624,664 A	11-1986	Peluso et al.	604/256
*	E	US-4,671,306 A	06-1987	Spector, Donald	132/73
*	F	US-4,778,447 A	10-1988	Velde et al.	604/29
*	G	US-5,195,957 A	03-1993	Tollini, Dennis R.	604/29
*	H	US-5,242,425 A	09-1993	White et al.	604/256
*	I	US-5,694,978 A	12-1997	Heilmann et al.	138/89
*	J	US-2003/0153865 A1	08-2003	Connell et al.	604/28
*	K	US-6,708,363 B2	03-2004	Larsen, L. Chris	15/104.92
*	L	US-2004/0258560 A1	12-2004	Lake et al.	422/028
*	M	US-6,911,025 B2	06-2005	Miyahara, Hideyasu	604/415

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 11/281,711	Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0124970 A1	06-2005	Kunin et al.	604/508
*	B	US-6,994,315 B2	02-2006	Ryan et al.	251/149.6
*	C	US-2006/0030827 A1	02-2006	Raulerson et al.	604/267
*	D	US-7,083,605 B2	08-2006	Miyahara, Hideyasu	604/415
*	E	US-7,198,611 B2	04-2007	Connell et al.	604/30
*	F	US-2007/0225660 A1	09-2007	Lynn, Lawrence Allan	604/265
*	G	US-7,452,349 B2	11-2008	Miyahara, Hiseyasu	604/415
*	H	US-7,682,561 B2	03-2010	Davis et al.	422/28
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	P					
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	R					
	S					
	T					

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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant				☐ CPA				☐ T.D.				☐ R.1.47			
CLAIM		DATE													
Final	Original	11/20/2009	06/08/2010												
	1	✓	✓												
	2	✓	-												
	3	✓	-												
	4	✓	✓												
	5	✓	-												
	6	✓	✓												
	7	✓	-												
	8	✓	✓												
	9	✓	✓												
	10	✓	-												
	11	N	-												
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	14	N	-												
	15	N	-												
	16	N	-												
	17	N	-												
	18	N	-												
	19	N	-												
	20	N	-												
	21		-												
	22		-												
	23		✓												
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	33		✓												
	34		✓												
	35		✓												
	36		✓												

Index of Claims 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant				☐ CPA				☐ T.D.				☐ R.1.47			
CLAIM		DATE													
Final	Original	11/20/2009	06/08/2010												
	37		✓												
	38		✓												
	39		✓												
	40		✓												
	41		✓												
	42		✓												
	43		✓												
	44		✓												

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

SEARCHED			
Class	Subclass	Date	Examiner
604	533, 265, 267	6/8/2010	AG

SEARCH NOTES			
Search Notes		Date	Examiner
Updated EAST class/subclass and keyword search done on 11/20/2009		6/8/2010	AG
Inventor Name and PLUS search		6/8/2010	AG
Forward/Backward citation searches		6/8/2010	AG

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW M GILBERT/ Examiner.Art Unit 3767	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
58233 7590 09/13/2010 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kinney & Lange) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 09/13/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

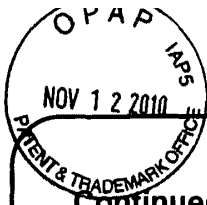
A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



11-15-10

RCE/FFu

**Request
for
Continued Examination (RCE)
Transmittal**

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	11/281,711
Filing Date	November 17, 2005
First Named Inventor	Minh Quang Hoang
Art Unit	3767
Examiner Name	Andrew M. Gilbert
Attorney Docket Number	B819.12-0004 P-6836
Express Mail No.	EM 299373289 US

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

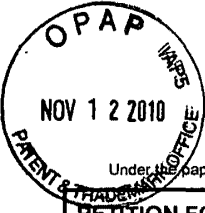
1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
- a. ☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Information Disclosure Statement (IDS)
- iii. ☐ Affidavit(s)/ Declaration(s)
- iv. ☐ Other _____
2. **Miscellaneous**
- a. ☐ Suspension of action on the above identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b. ☐ Other _____
3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- a. ☒ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 11-0982.
- i. ☐ RCE fee required under 37 CFR 1.17(e)
- ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☒ Check in the amount of \$ 1,960.00 _____ enclosed
- c. ☐ Payment by credit card (Form PTO 2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO 2038.

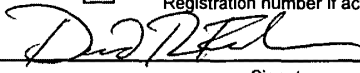
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Signature		Date	11/12/10
Name (Print/Type)	David R. Fairbairn	Registration No.	26,047

11/16/2010 RELEASED 68222336 11281711

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2009 <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number (Optional) B819.12-0004 P-6836
Application Number 11/281,711		Filed November 17, 2005
For PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER		
Art Unit 3767		Examiner Andrew M. Gilbert
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.		
The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):		
	<u>Fee</u>	<u>Small Entity Fee</u>
☐ One month (37 CFR 1.17(a)(1))	\$130	\$65 \$ _____
☒ Two months (37 CFR 1.17(a)(2))	\$490	\$245 \$ <u>490.00</u>
☐ Three months (37 CFR 1.17(a)(3))	\$1110	\$555 \$ _____
☐ Four months (37 CFR 1.17(a)(4))	\$1730	\$865 \$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$2350	\$1175 \$ _____
☐ Applicant claims small entity status. See 37 CFR 1.27.		
☒ A check in the amount of the fee is enclosed.		
☐ Payment by credit card. Form PTO-2038 is attached.		
☐ The Director has already been authorized to charge fees in this application to a Deposit Account.		
☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>11-0982</u> .		
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.		
I am the ☐ applicant/inventor.		
☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).		
☒ attorney or agent of record. Registration Number <u>26,047</u>		
☐ attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		
 Signature		<u>11/12/10</u> Date
<u>David R. Fairbairn</u> Typed or printed name		<u>612-339-1863</u> Telephone Number
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.		
☒ Total of <u>1</u> forms are submitted.		

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: Minh Quang Hoang	
Appln. No.	: 11/281,711	Confirmation No.: 9168
Filed	: November 17, 2005	Group Art Unit: 3767
Title	: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	Examiner: Andrew M. Gilbert
Docket No.	: B819.12-0004 P-6836	

AMENDMENT AFTER FINAL

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FILED VIA EXPRESS MAIL

EXPRESS MAIL NO.: EM 299373289 US

INTRODUCTION

This Amendment After Final accompanies a Request for Continued Examination (RCE) is in response to the Office Action mailed June 11, 2010. Please amend the above-identified application as follows:

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 27, and 36, cancel claims 4, 6, 8, 24, 26, 28-33, 35, 37-42, and 44 and add new claims 45-60, such that the status of the claims is as follows:

1. (Currently amended) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing for covering the access portion of the access valve, the housing having an open end, a closed end, and a cavity, the housing including a helical thread on an inner wall of the cavity for engaging the external threads on the access portion of the access valve, the helical thread having an outer end adjacent the open end and having an inner end;

a wet pad ~~containing a~~ comprising a sponge formed of a material from the group consisting of polyurethane, polyester, cotton, and silicone, and an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution, the wet pad positioned within the cavity adjacent the inner end of the helical thread for contacting the end face of the access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity so that the end face of the access portion contacts the wet pad.

2-8. (Canceled)

9. (Previously presented) The device of claim 1 wherein the wet pad contains an antimicrobial agent.

10-22. (Canceled)

23. (Previously presented) The device of claim 9, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

24. (Canceled)

25. (Previously presented) The device of claim 1, wherein the housing is formed of a polyethylene or polypropylene material.

26. (Canceled)

27. (Currently amended) A device for antiseptically maintaining a patient fluid line access valve, the device comprising:

- a cap with a single cavity for covering an access portion of the access valve, the access portion including an exposed surface of a septum of the access valve and at least a portion of an exposed surface of a housing of the access valve that surrounds the septum;

- a wet pad within the single cavity and containing a cleaning solution, the wet pad for contacting the access portion of the access valve to apply the cleaning solution to the access portion to reduce the amount of microbes on the access portion wherein the wet pad comprises a sponge made of a material from the group consisting of polyurethane, polyester, and silicone, an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution and an antimicrobial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate;

- a thread on a wall of the inner cavity of the cap having an outer end positioned close to an opening to the cavity and having an inner end positioned close to the

wet pad for engaging the patient fluid line access valve to contact the wet pad to the access portion of the access valve; and

a lid for providing a moisture barrier over the wet pad, the lid being removable to allow the cap to be placed over the access portion of the access valve with the wet pad in contact with the access portion.

28-33. (Canceled)

34. (Previously presented) The device of claim 27, wherein the cap is formed of a polyethylene or polypropylene material.

35. (Canceled)

36. (Currently amended) A device for maintaining a threaded patient fluid line access valve, the device comprising:

a housing having an inner cavity for covering an end face of the access valve;
a wet pad within the housing and containing a cleaning solution, the wet pad for contacting at least a portion of the threaded patient fluid line access valve and the end face of the access valve to reduce the amount of microbes on the access valve, wherein the wet pad comprises a sponge made of a material from the group consisting of polyurethane, polyester, and silicone, an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution and an antimicrobial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate;
a thread within the inner cavity of the housing having an outer end positioned close to an opening to the cavity and having an inner end positioned close to the wet pad for engaging the threaded patient fluid line access valve to contact the wet pad to the end face of the access valve; and

a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the end face of the access valve to be inserted into the housing and contact the wet pad.

37. (Currently amended) The device of claim 36, wherein the housing includes a thread within the inner cavity for engaging an external thread on the access valve.

38-42. (Canceled)

43. (Previously presented) The device of claim 36, wherein the housing is formed of a polyethylene or polypropylene material.

44. (Canceled)

45. (New) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum, the device comprising:

a housing for covering the access portion of the access valve, the housing having an open end, a closed end, and a cavity;

a wet pad ~~containing a~~ comprising a sponge formed of a material from the group consisting of polyurethane, polyester, cotton, and silicone, and an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution, the wet pad positioned within the cavity for contacting the end face of the access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the

wet pad and allow insertion of the access portion of the access valve into the cavity so that the end face of the access portion contacts the wet pad.

46. (New) The device of claim 45 wherein the housing includes a thread within the cavity for engaging an external thread on the access valve.

47. (New) The device of claim 45 wherein the wet pad contains an antimicrobial agent.

48. (New) The device of claim 47, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

49. (New) The device of claim 45, wherein the housing is formed of a polyethylene or polypropylene material.

50. (New) The device of claim 45, wherein the housing includes an outwardly extending flange at the open end, and wherein the lid is attached to the flange to seal the cavity.

51. (New) The device of claim 45, wherein the cavity is sized to allow lateral movement of the cap with respect to the access valve for cleaning of the septum by the wet pad when the access valve is inserted into the cavity.

52. (New) A device for antiseptically maintaining a patient fluid line access valve, the device comprising:

a cap with a single cavity for covering an access portion of the access valve, the access portion including an exposed surface of a septum of the access valve and at least a portion of an exposed surface of a housing of the access valve that surrounds the septum;

a wet pad within the single cavity for contacting the access portion of the access

valve to apply the cleaning solution to the access portion to reduce the amount of microbes on the access portion, wherein the wet pad comprises a sponge made of a material from the group consisting of polyurethane, polyester, and silicone, an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution and an antimicrobial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate; and a lid for providing a moisture barrier over the wet pad, the lid being removable to allow the cap to be placed over the access portion of the access valve with the wet pad in contact with the access portion.

53. (New) The device of claim 52, wherein the cap is formed of a polyethylene or polypropylene material.

54. (New) The device of claim 52, wherein the housing includes an outwardly projecting flange at an open end of the cap, and wherein the lid is attached to the flange.

55. (New) The device of claim 52, wherein the cavity is sized to allow lateral movement of the cap with respect to the access valve for cleaning of the septum by the wet pad when the access valve is inserted into the cavity.

56. (New) A device for maintaining a patient fluid line access valve, the device comprising:
a housing having an inner cavity for covering an end face of the access valve;
a wet pad within the housing contacting the end face of the access valve to reduce the amount of microbes on the access valve; and
wherein the wet pad comprises a sponge made of a material from the group consisting of polyurethane, polyester, and silicone, an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution and an antimicrobial agent that includes at least one of chlorhexidine gluconate and

chlorhexidine diacetate; and
a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the end face of the access valve to be inserted into the housing and contact the wet pad.

57. (New) The device of claim 56, wherein the housing includes a thread within the inner cavity for engaging an external thread on the access valve.

58. (New) The device of claim 56, wherein the housing is formed of a polyethylene or polypropylene material.

59. (New) The device of claim 56, wherein the housing includes an outwardly projecting flange at an open end of the cap, and wherein the lid is attached to the flange.

60. (New) The device of claim 56, wherein the cavity is sized to allow lateral movement of the cap with respect to the access valve for cleaning of the septum by the wet pad when the access valve is inserted into the cavity.

REMARKS

This Amendment After Final accompanies a Request for Continued Examination (RCE), and is in response to the Office Action mailed June 11, 2010, in which claims 1, 4, 6, 8, 9, and 23-44 were rejected. With this Amendment, claims 1, 27, and 36 have been amended; claims 4, 6, 8, 24, 26, 28-33, 35, 37-42, and 44 are cancelled; and new claims 45-60 are added. Claims 1, 9, 23, 25, 27, 34, 36, 43, and 45-60 are now in the application and are presented for reconsideration and allowance.

On September 9, 2010, a telephone conference was conducted by Examiner Andrew M. Gilbert and Applicant's attorney David R. Fairbairn. During the telephone conference, proposed changes to independent claims 1, 27, and 36 were discussed and compared to the prior art references relied upon in the Office Action dated June 11, 2010 (White et al. U.S. Patent No. 5,242,425 and Lake, Jr. U.S. Pub. No. 2004/0258560), as well as the Menyhay U.S. Patent No. 5,554,135 which had been relied upon in rejecting claims in the previous Office Action of November 25, 2009. Although no agreement was reached in the course of the telephone conference, the discussion proved helpful in formulating the amendments to the claims that are presented with this Amendment After Final. Applicant thanks Examiner Gilbert for the opportunity to discuss this application and particularly the proposed claim amendments and the White, Lake, and Menyhay references.

In the Office Action dated June 11, 2010, all of the pending claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over White et al. (U.S. Patent No. 5,242,425) in view of Lake, Jr. et al. (U.S. Pub. No. 2004/0258560). Each of the independent claims 1, 27, and 36 have been amended to more specifically define the cap or housing, as well as the wet pad that is located within the cavity of the cap or housing. With these amendments, independent claims 1, 27, and 36 define a device that is neither taught nor suggested by White and Lake.

In particular, claim 1 has been amended to specify that the device is for maintaining a patient fluid line access valve of a type that has an access portion with an end face that includes a septum and external threads on the access portion proximate the septum. The device is configured to mate with this type of access valve, which is different than the type of valve shown in White, and is

different from the stethoscope shown in Lake. To mate with the access valve, the housing of the claimed device includes a helical thread on an inner wall of the cavity that engages the external threads on the access portion of the access valve. The helical thread has an outer end adjacent to the open end of the housing and an inner end that is adjacent to the wet pad.

Claim 1 has also been amended to more specifically define the wet pad. In particular, the wet pad comprises a sponge and an alcohol based cleaning solution. Amended claim 1 specifies the materials from which the sponge is formed and the alcohol concentration of the alcohol based cleaning solution. Claim 1 also includes a lid over the open end of the housing to seal the cavity. In other words, the wet pad is maintained in a wet condition prior to use. There can be a significant time between when the device is manufactured and the wet pad is loaded with the 50% to 100% alcohol solution. It is important that the device maintain its effectiveness throughout its shelf life, before it is placed into use by removal of the lid and insertion of the access portion of an access valve into the cavity of the housing. A loss of cleaning and antimicrobial effectiveness of the wet pad prior to use is an important factor. The particular group of materials from which the sponge is formed, and the particular cleaning solution used address the shelf life issue.

Claim 27 has been amended to include the thread on the inner wall of the inner cavity of the cap and to define the wet pad. The wet pad comprises a sponge made of a material from the group consisting polyurethane, polyester, and silicone, an alcohol-based cleaning solution containing about 50% to about 100% alcohol solution and an antimicrobial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

As discussed with respect to claim 1, the ability of the wet pad to maintain its characteristics during storage prior to use is an important factor. The materials forming the sponge, as defined in amended claim 27, are compatible with the alcohol-based cleaning solution and the antimicrobial agent so that the effectiveness of the wet pad can be maintained during the self life of the product until it is placed into use.

Independent claim 36 has also been amended to specify the threaded inner connection of the device with the access valve and to define the wet pad as including the sponge made of a material from the group consisting polyurethane, polyester, and silicone, an alcohol-based cleaning

solution containing about 50% to about 100% alcohol solution, and an antimicrobial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

Dependent claim 9 states that the wet pad contains an antimicrobial agent, and dependent claim 23 states that the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

Dependent claim 25 specifies that the housing is formed of a polyethylene or polypropylene material. These materials have been found to be advantageous because the materials are compatible with the wet pad so that the effectiveness of the wet pad is not compromised during its storage life. Claims 34 and 43 are similar to dependent claim 25 in specifying that the cap or housing is formed of polyethylene or polypropylene material.

As amended, independent claims 1, 27, and 36, as well as dependent claims 9, 23, 25, 34, and 43 describe a device that is neither taught nor suggested by White and Lake. The rejection of those claims under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed.

During the telephone conference on September 9, 2010, Examiner Gilbert mentioned Menyhay U.S. Patent No. 5,554,135 which had been cited in the previous Office Action of November 25, 2009, and suggested that any amendment to the claims take into account Menyhay as well as White and Lake. Menyhay describes a device that is different from the present invention in that Menyhay has a separate sealed chamber that contains a cleaning solution. This chamber is positioned behind a dry pad within the cavity of the device. When an access valve is inserted into Menyhay's device, a force is applied that is sufficient to cause the chamber containing the cleaning solution to be punctured or ruptured so that the dry pad can be filled with the cleaning solution. Thus, Menyhay avoids the problem that the present invention addresses: how to maintain a wet pad ready to use throughout its shelf life, without having a negative effect on the cleaning and antimicrobial capabilities of the wet pad. The approach taken by Menyhay results in a device that is more complex than the device of the present invention.

The present invention uses a lid over the open end to seal the cavity (and thus prevent the wet pad from drying out). In addition, the device as defined in independent claims 1, 27, and 36, as well as the dependent claims, makes use of wet pad and housing materials that are compatible

First Named Inventor: Minh Quang Hoang

Application No.: 11/281,711

-12-

with one another so that the device will be effective when it is finally placed into use. The device of the present invention, as defined in claims 1, 9, 23, 25, 27, 34, 36, and 43 is not taught nor suggested by White, Lake, or Menyhay.

New claims 45-60 have also been presented. These claims also address the issue of a device that includes a housing or cap, a wet pad, and a lid, where the effectiveness of the wet pad and particularly the alcohol solution and any antimicrobial agent within the wet pad can be maintained during the shelf life. This is achieved by the use of particular materials for the sponge and particular solutions and antimicrobial agents that are compatible with the sponge. Claims 45-60 are neither taught nor suggested by the prior art of record, and should be allowed.

In summary, claims 1, 9, 23, 25, 27, 34, 36, 43, and 45-60 are in condition for allowance. Notice to that effect is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.16 and 1.17, or credit any overpayment, to Deposit Account No. 11-0982.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: 11/12/10

By: 

David R. Fairbairn, Reg. No. 26,047

THE KINNEY & LANGE BUILDING

312 South Third Street

Minneapolis, MN 55415-1002

Telephone: (612) 339-1863

Fax: (612) 339-6580

DRF:ks



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: Minh Quang Hoang	Confirmation #:	9168
Appln. No.	: 11/281,711	Group Art Unit:	3767
Filed	: November 17, 2005	Examiner:	Andrew M. Gilbert
Title	: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER		
Docket No.	: B819.12-0004 P-6836		

EXPRESS MAIL COVER SHEET

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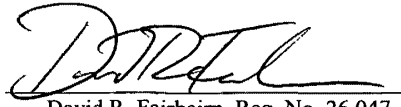
The following papers are being transmitted via **EXPRESS MAIL** to the U.S.
Patent and Trademark Office on the date shown below:

1. A Check in the Amount of \$1,960.00 (RCE, extra claim, two month extension time fees).
2. Fee Transmittal Sheet.
3. Request for Continued Examination (RCE) Transmittal.
4. Amendment After Final.
5. Petition for Two Month Extension of Time.
6. Return Receipt Postcard.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: 11/12/10

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Signature David R. Fairbairn Reg. No. 26,047

Date 11/12/10 Deposit Account No. 11-0982

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed		
APPLICATION AS FILED – PART I											
(Column 1)			(Column 2)		SMALL ENTITY ☐		OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)			RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A				N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A				N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A				N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	OR		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.											
TOTAL					TOTAL						
APPLICATION AS AMENDED – PART II											
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	11/12/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 25	Minus	** 27	= 0	X \$	=	OR		X \$52=	0
	Independent (37 CFR 1.16(h))	* 6	Minus	***3	= 3	X \$	=	OR		X \$220=	660
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
						TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE	
TOTAL					TOTAL				TOTAL		660
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR		X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR		X \$	=
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
						TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE	
TOTAL					TOTAL				TOTAL		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Legal Instrument Examiner:
/NINA RATANAVONG/

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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/281,711
	Filing Date	November 17, 2005
	First Named Inventor	Minh Quang Hoang
	Title	Patient Fluid Line Access Valve Antimicro..
	Art Unit	3767
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.**OR**☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

71562

OR☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.**OR**☐ The address associated with Customer Number:

71562

OR☒ Firm or Individual Name **Craig Metcalf of Kirton & McConkie**

Address

City

State

Zip

Country

Telephone

Email

I am the:

☐ Applicant/Inventor.**OR**☒ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Assignee of Record

Signature	/Craig Metcalf/	Date	February 7, 2012
Name	Craig Metcalf	Telephone	801-328-3600
Title and Company	Attorney		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Minh Quang Hoang et al.

Application No./Patent No.: 11/281,711

Filed/Issue Date: November 17, 2005

Titled: Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner

Becton, Dickinson and Company, a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest in;
2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 017252, Frame 0614, or for which a copy therefore is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature

David W. Highet

Printed or Typed Name

Date

2/3/12
Sr. VP and Chief IP Counsel

Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	12022021
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	58233
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	07-FEB-2012
Filing Date:	17-NOV-2005
Time Stamp:	18:03:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	P_6836_Revoke_POA_020712.pdf	193763 a2850db8ca0275dbe059d2419bb72b8697b8da87	no	4

Warnings:

Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/281,711	11/17/2005	Minh Quang Hoang	P-6836

CONFIRMATION NO. 9168

POWER OF ATTORNEY NOTICE



OC000000052589782

58233
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kinney & Lange)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

Date Mailed: 02/16/2012

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/07/2012.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/281,711	11/17/2005	Minh Quang Hoang	P-6836

CONFIRMATION NO. 9168

POA ACCEPTANCE LETTER



OC000000052590392

71562

David W. Highet, VP & Chief IP Counsel

Becton, Dickinson and Company

(Kirtan & McConkie)

1 Becton Drive, MC 110

Franklin Lakes, NJ 07417-1880

Date Mailed: 02/16/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/07/2012.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 04/10/2012 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 04/10/2012	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 12 November 2010.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,9,23,25,27,34,36,43 and 45-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,9,23,25,27,34,36,43 and 45-60 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 17 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2010 has been entered.

Acknowledgments

1. The applicant amended claims 1, 27, 36; claims 4, 6, 8, 24, 26, 28-33, 35, 37-42 were cancelled; and new claims 45-60 were added.
2. Thus, claims 1, 9, 23, 25, 27, 34, 36, 43 and 45-60 are pending for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 52 recites the limitation "the cleaning solution" in ln 8. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 54 recites the limitation "the housing" in ln 1. There is insufficient antecedent basis for this limitation in the claim.
5. Claims 27, 36, 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 27, 36, and 52 recite that the wet pad

contains "a cleaning solution" (i.e. claim 27, ln 3) and "an alcohol-based cleaning solution" (i.e. claim 27, lns 8-9). It is unclear whether the applicant intends for "a cleaning solution" to be the alcohol-based cleaning solution to be or whether there are two cleaning solutions contained in the wet pad. The examiner believes the applicant intended to recite only a single cleaning solution being the alcohol-based cleaning solution. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 9, 23, 27, 36, 37, 45- 48, 50-52, 54-57, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (5242425) in view of Busch (2004/0004019). White et al discloses a device for maintaining a patient fluid line access (18; Fig 1) having an access portion with an end face that includes a septum (54 or 84; Fig 7); the device comprising: a housing (78), having an open end (74), a closed end (Fig 7) and a cavity (Fig 7; see where valve and septum 84 are inserted into the cavity in Fig 7), a wet pad being a sponge (80) containing a cleaning solution (Summary; col 3, lns 36-40; col 6, lns 52-58) for contacting the end face of the access portion of the access valve (Summary); a thread within the cavity for engaging an external thread on the access valve (76; Fig 7); the wet pad containing an antimicrobial

agent (Summary; col 3, Ins 36-40; col 6, Ins 52-58) and the cavity being sized to allow for lateral movement of the cap with respect to the access valve (Fig 7).

5. With regards to independent claims 1, 27, 36, White further teaches a thread (76; Fig 7) on the inner cavity of the cap having an outer end position close to an opening to the cavity (Fig 7) and an inner end positioned close to the wet pad (Fig 7; where the Examiner notes "close to" in a broad and relative term and the thread 76 here in White et al can be reasonably interpreted to end close to the wet pad; further the Examiner notes that the size of the valve and cap is relatively very small).

6. However, White et al does not appear to disclose a removable lid over the open end of the housing to seal the cavity with the wet pad to provide a moisture barrier or the wet pad's sponge being formed from the claimed material and having an alcohol-based cleaning solution containing about 50%-100% alcohol and anti-microbial agent that includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

7. Busch teaches that it is known to have a removable lid (24) over the open end of a housing (12) and secured to a projecting flange of the housing (see lip on housing 12 in Figs 1-2) to seal the cavity with the wet pad (28) being a sponge having an antiseptic solution of chlorohexadine or chloridexadine gluconate (§26) with a solution of 70% isopropyl alcohol (§26) to provide first a lid to provide moisture barrier for the purpose of maintaining the sterility of the device prior to use and preventing the sponge from drying out and then to provide a antiseptic solution that can quickly dry upon application. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by White et al with the flange and lid (here the

flange and lid would be provided at the end (near 76 in Fig 7) of the housing 78) and specific cleaning and antimicrobial agent as taught by Busch for the purpose to first provide a lid to provide moisture barrier for the purpose of maintaining the sterility of the device prior to use and preventing the sponge from drying out and then to provide a antiseptic solution that can quickly dry upon application.

8. Claim 25, 34, 43, 49, 53, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Busch in further view of Velde et al (4778447). White et al and Busch discloses the invention substantially as claimed except for expressly disclosing the housing is formed of a polyethylene or polypropylene material. Velde et al teaches that it is known to have the housing formed of a polyethylene or polypropylene material (col 3, lns 43-57) for the purpose of providing an ultra-violet transparent material for the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cap material as taught by White et al in view of Busch with the polypropylene material as taught by Velde et al for the purpose of providing an ultra-violet transparent material for the cap.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 form. The Examiner notes that Genatempo et al

(USPN 4440207) shows the flange and lid as claimed (see Fig 2). Other cited references are pertinent but are not prior art due to their effective filing dates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M. Gilbert/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

Notice of References Cited	Application/Control No. 11/281,711	Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3767	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,440,207	04-1984	Genatempo et al.	150/154
*	B	US-4,778,447	10-1988	Velde et al.	604/29
*	C	US-5,242,425	09-1993	White et al.	604/256
*	D	US-2004/0004019	01-2004	Busch, L. John	206/571
*	E	US-5,639,310	06-1997	Giampaolo, Jr., Joseph L.	134/6
*	F	US-5,817,344	10-1998	Hoang et al.	424/667
*	G	US-8,065,773	11-2011	Vaillancourt et al.	15/104.94
*	H	US-7,922,701	04-2011	Buchman, Alan L.	604/256
*	I	US-8,113,731	02-2012	Cable et al.	401/134
*	J	US-7,704,935	04-2010	Davis et al.	510/131
*	K	US-2009/0062766	03-2009	Howlett et al.	604/411
*	L	US-2009/0028750	01-2009	Ryan, Dana Wm.	422/28
*	M	US-2008/0147047	06-2008	Davis et al.	604/533

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant					☐ CPA					☐ T.D.					☐ R.1.47				
CLAIM		DATE																	
Final	Original	11/20/2009	06/08/2010	04/04/2012															
	1	✓	✓	✓															
	2	✓	-	-															
	3	✓	-	-															
	4	✓	✓	-															
	5	✓	-	-															
	6	✓	✓	-															
	7	✓	-	-															
	8	✓	✓	-															
	9	✓	✓	✓															
	10	✓	-	-															
	11	N	-	-															
	12	N	-	-															
	13	N	-	-															
	14	N	-	-															
	15	N	-	-															
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	19	N	-	-															
	20	N	-	-															
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	22		-	-															
	23		✓	✓															
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	31		✓	-															
	32		✓	-															
	33		✓	-															
	34		✓	✓															
	35		✓	-															
	36		✓	✓															

Index of Claims 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant										☐ CPA										☐ T.D.										☐ R.1.47									
CLAIM		DATE																																					
Final	Original	11/20/2009	06/08/2010	04/04/2012																																			
	37		✓	-																																			
	38		✓	-																																			
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	60			✓																																			

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

SEARCHED			
Class	Subclass	Date	Examiner
604	533, 265, 267	4/4/2012	AG

SEARCH NOTES			
Search Notes		Date	Examiner
Updated EAST class/subclass and keyword search done on 6/8/2010		4/4/2012	AG
Inventor Name and PLUS search		4/4/2012	AG
Forward/Backward citation searches		4/4/2012	AG

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW M GILBERT/ Examiner.Art Unit 3767	



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 05/30/2012 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 05/30/2012	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 11/281,711 Confirmation No.: 9168
Applicants : Minh Quang Hoang et al.
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Filed : November 17, 2005
TC/A.U. : 3767
Examiner : Andrew M. Gilbert
Docket No. : P-6836
Customer No. : 71562

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is being submitted in response to the Office Action mailed April 10, 2012 (the "Office Action"). Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed is:

1-33. (Cancelled)

34. (Currently amended) The device of claim 61 27, wherein the cap device is formed of a polyethylene or polypropylene material.

35. (Previously cancelled)

36. (Cancelled)

37. (Currently amended) The device of claim 67 36, wherein the ~~housing includes a thread~~ set of threads within the ~~inner~~ cavity are configured for engaging to engage an external thread on ~~the~~ an access valve.

38-42. (Cancelled)

43. (Currently amended) The device of claim 67 36, wherein the ~~housing~~ body is formed of a polyethylene or polypropylene material.

44. (Previously cancelled)

45. (Cancelled)

46. (Cancelled)

47. (Currently amended) The device of claim 68 45 wherein the ~~wet~~ pad contains an antimicrobial agent.

48. (Currently amended) The device of claim 47, wherein the antimicrobial agent includes at least one of chlorhexidine gluconate and chlorhexidine diacetate.

49. (Currently amended) The device of claim 68 45, wherein the ~~housing~~ body is formed of a polyethylene or polypropylene material.

50. (Currently amended) The device of claim 68 45, wherein the ~~house~~ body further includes ~~include~~ an outwardly extending flange at the an open end, and wherein ~~the~~ a lid is attached to the flange to seal the cavity.

51. (Currently amended) The device of claim 68 45, wherein the cavity is sized to allow lateral movement of the cap with respect to the patient fluid line access valve for cleaning of ~~the~~ a septum of the patient fluid line access valve by the ~~wet~~ pad when the patient fluid line access valve is inserted into the cavity.

52-60. (Cancelled)

61. (New) A cap device comprising:

a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall;

a pad holding a cleaning solution, the pad being seated within the cavity and contacting the proximal end; and

a set of threads comprising a portion of the internal wall, a portion of the threads being configured to contact the pad.

62. (New) The device of claim 61, wherein the set of threads is configured to threadedly receive a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum.

63. (New) The device of claim 62, wherein the set of threads threadedly receives the external threads thereby causing the interface to advance into the cavity such that the septum contacts the pad.

64. (New) The device of claim 63, wherein a threaded interaction between the set of threads and the external threads provides adjustable positioning of the septum within the cavity.

65. (New) The device of claim 61, wherein the pad is a wet pad comprising a sponge.

66. (New) The device of claim 63, wherein adjustable positioning of the septum within the cavity allows the septum to contact the pad, and further allows the septum to contact and compressed the pad between the septum and the proximal end.

67. (New) A cap device comprising:

a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall;

a pad seated within the cavity and contacting the proximal end; and

a set of threads comprising a portion of the internal wall, the threads having a proximal end and a distal end, the proximal end of the threads being in contact with the pad.

68. (New) A cap device comprising:

a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall;

a pad seated within the cavity and contacting the proximal end, the pad having a distal surface that is compressible from a resting position to a compressed position; and

a set of threads comprising a portion of the internal wall, the threads being configured to threadedly receive a patient fluid line access valve to a depth sufficient to compress the pad from the resting position to the compressed position.

REMARKS/ARGUMENTS

This paper is filed in response to the Office Action of April 10, 2012. In the Office Action, claims 27, 36, 52 and 54 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, claims 1, 9, 23, 27, 36, 37, 45-48, 50-52, 54-57 and 59-60 were rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (US Patent No. 5,242,425) in view of Busch (2004/0004019), and claims 25, 34, 43, 49, 53 and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over White in view of Busch, and further in view of Velde et al (US patent No. 4,778,447).

By this paper, claims 34, 37, 43 and 47-51 have been amended, claims 1, 9, 23, 25, 27, 36, 45, 46 and 52-60 have been canceled, and new claims 61-68 have been added. Support for these amendments and new claims is found generally throughout the application, and more specifically at page 8, lines 1-19, and Figures 10A and 10B. Accordingly, claims 34, 37, 43, 47-51, and 61-68 are presented for reconsideration and/or immediate allowance by the Examiner.

Examiner's In-Person Interview

Applicants express appreciation to Examiner Gilbert for conducting an in-person interview with Applicants' attorneys on May 24, 2012. During the interview, Examiner Gilbert and Applicants' attorneys discussed the application, the outstanding Office Action, and ways to overcome the prior art.

Rejections Under 35 U.S.C. §103(a) over White in view of Busch

In the Office Action, the Examiner rejected claims 1, 9, 23, 27, 36, 37, 45-48, 50-52, 54-57 and 59-60 under 35 U.S.C. §103(a) as being unpatentable over White in view of Busch. M.P.E.P. § 2141 sets forth the Graham factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Citing Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In addition, M.P.E.P. §§ 2141 and 2142 set forth that “the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” *Citing KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Accordingly, Applicants respectfully submit that 1) the references in the Office Action, either alone or in combination, do not teach or suggest all the limitations claimed in the amended claim set provided herein. Applicants also respectfully submits that 2) the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

Applicants submit that the claims, as presently amended, are patentable over the combined teachings of the cited prior art references. In particular, none of the cited references, alone or in combination, teach a cap device comprising “a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall; a pad holding a clean solution, the pad seated within the cavity and contacting the proximal end; and a set of threads comprising a portion of the internal wall, a portion of the threads being configured to contact the pad.” *See* amended claim 61, above. Further, the combined references fail to

teach a "cap device comprising: a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall; a pad seated within the cavity and contacting the proximal end; and a set of threads comprising a portion of the internal wall, the threads having a proximal end and a distal end, a proximal end of the threads being in contact with the pad." *See* claim 67, above.

Rather, White teaches an outer protective cap 78 which includes a sponge 80 that is positioned distally from internal threads 76 and the threaded shoulder 74. *See* White at Figure 7, and Col. 7, lines 23-41. Accordingly, White is entirely devoid of any teaching whereby sponge 80 is configured to contact threads 76. Further, Busch is relied upon solely for the teaching of a removable lid over the open end of the housing to seal the cavity with the wet pad, thereby providing a moisture barrier. As such, neither White nor Busch teach or suggest the features of the invention as presently claimed. Accordingly, applicants request withdrawal of the present rejections.

Applicants further submit that the combined references fail to teach a "cap device comprising: a body having a proximal end, a distal opening, and a cavity extending therebetween, the cavity comprising an internal wall; a pad seated within the cavity and contacting the proximal end, the pad having a distal surface that is compressible from a resting position to a compressed position; and a set of threads comprising a portion of the internal wall, the threads being configured to receive a patient fluid line access valve to a depth sufficient to compress the pad from the resting position to the compressed position." *See* claim 68, above. Rather, a shelf portion of threads shoulder 74 of White necessarily limits the depth of insertion of self-ceiling septum 84 into sponge 80. *See* White at Figure 7. Accordingly,

the outer protective cap 78 of White is configured to limit the depth of insertion of septum 84 into cap 78. In particular, cap 78 is configured such that septum 84 is permitted merely to contact sponge 80, but not advance septum 84 into sponge 80 to compressed sponge 80. Applicants therefore request withdrawal of the present rejections.

Rejections Under 35 U.S.C. §103(a) over White in view of Busch

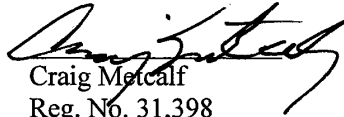
In the Office Action, the Examiner further rejected claims 25, 34, 43, 49, 53 and 58 under 35 U.S.C. §103(a) as being unpatentable over White in view of Busch and Velde. Applicants submit that the combined teachings of the cited references fail to teach the features of the invention as presently claimed. In particular, Applicants submit that Velde fails to teach those features of the present invention which have previously been shown to be absent in the combined teachings of White and Busch. In the Office Action, the Examiner states that “White et al and Busch discloses the invention substantially as claimed except for expressly disclosing the housing is formed of a polyethylene or polypropylene material.” See Office Action at page 5. As such, the Examiner cites Velde for this teaching. Aside from this teaching, Velde is entirely devoid of any teaching which includes the structural features of the invention, as presently claimed. Thus, Applicants submit that the combined teachings of the cited references fail to teach the features of the present invention, as discussed above. Applicants therefore request withdrawal of the present rejections.

Appl. No. 11/281,711
Amdt. dated June 28, 2012
Reply to Office Action of April 10, 2012

Conclusion

In light of the foregoing, Applicants respectfully submit that the claims as amended are in condition for immediate allowance. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is respectfully requested to call the undersigned.

Respectfully submitted,


Craig Metcalf
Reg. No. 31,398
Attorney for Applicant

Date: June 28, 2012

KIRTON | McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone: 801-328-3600

Electronic Acknowledgement Receipt	
EFS ID:	13129469
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	28-JUN-2012
Filing Date:	17-NOV-2005
Time Stamp:	13:23:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P_6836_OAResp_062812.pdf	316405 b3cfeb7bb3c009005b178004d6bc17e436b25d78d	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	10
Warnings:			
Information:			
Total Files Size (in bytes):		316405	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed	
APPLICATION AS FILED – PART I									
		(Column 1)	(Column 2)	SMALL ENTITY ☐ OR		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A			
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A			
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A			
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL			
APPLICATION AS AMENDED – PART II									
		(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	11/12/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(o))	* 25	Minus	** 27 = 0	X \$ =		OR	X \$52=	0
	Independent (37 CFR 1.16(h))	* 6	Minus	*** 3 = 3	X \$ =		OR	X \$220=	660
	☐ Application Size Fee (37 CFR 1.16(s))						OR		
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	660
AMENDMENT	6.28.12	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(o))	* 16	Minus	** 27 = 6	X \$ =		OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 16 = 6	X \$ =		OR	X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))						OR		
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

Legal Instrument Examiner:
/NINA RATANAVONG/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562	7590	09/25/2012		
David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 09/25/2012	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

Office Action Summary	Application No.	Applicant(s)	
	11/281,711	HOANG ET AL.	
	Examiner	Art Unit	
	ANDREW GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 28 June 2012.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 34,37,43,47-51 and 61-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 34,37,43,47-51 and 61-68 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 17 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. The applicant amended claims 34, 37, 43, 47-51; claims 1, 9, 23, 25, 27, 36, 45, 46, and 52-60 were cancelled; and new claims 61-68 were added.
2. Thus, claims 34, 37, 43, 47-51, and 61-68 are pending for examination.

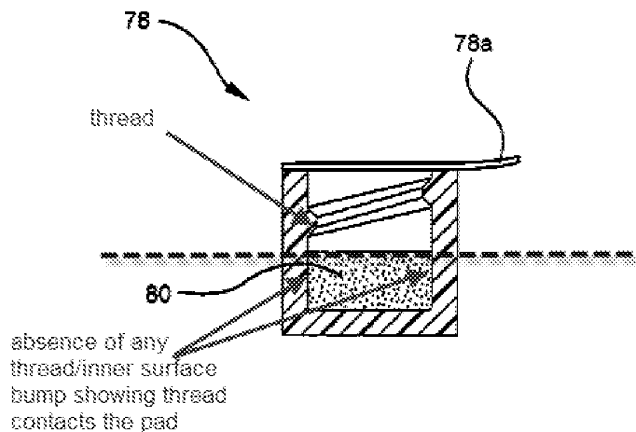
Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 34, 37, 43, and 61-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 61, 67 recite that a portion or the proximal end of the threads on the internal wall of the cap are in contact with the pad. However, the applicant's cited support of page 8, lns 1-19 and Figs 10a-b fail to reasonably convey that the applicant had possession of this aspect of the claimed invention.
3. As shown in annotated Fig 10b below, there is no disclosure of the thread contacting the pad.

FIG. 10B



4. Further, pg 8, lns 1-19 (also ¶¶42-46 of the published application) fails to teach or suggest the proximal end or a portion of the thread contacting the pad.

[0042] FIG. 10A shows a representative embodiment of cleaning device 74 with lid 74a and wet pad 76. Here, cleaning device 74 is a stand-alone device that is used as described above for cleaning end 16.

[0043] FIG. 10B shows a representative embodiment of cap device 78 with lid 78a and pad 80. Cap device 78 is a stand-alone device where pad 80 may either be a wet pad or a dry pad. Where pad 80 is a dry pad, cap device 78 is used as described above for cap end 14.

[0044] Where pad 80 is a wet pad, cap device 78 may be used to clean access portion A10 of valve A in addition to its capping function. The twisting motion involved in removing and placing cap device 78 with respect to access portion A10 provides friction for cleaning. Additional cleaning can be accomplished by twisting cap device 78 in one direction and then in the reverse direction for a desired amount of time.

[0045] With either cleaning device 74 or cap device 78, additional gripping surface may be added by extending the length of the housing. The increased gripping surface would provide easier handling of devices 74 and 78.

[0046] Cap/cleaner 10 cleans and maintains access valves in antiseptic or aseptic condition. This substantially decreases the risk of patient infections caused by the ingress of microbes into the access valves, particularly for needleless access valves.

5. As show in the cited paragraphs above, there is no disclosure in the cited support or further anywhere in the originally filed specification for the amendment of a portion or proximal end of the thread contacting the pad.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim*** rejected under 35 U.S.C. 102(b) as being anticipated by Menyhay (5554135).
8. With regards to claim 68, Menyhay discloses a cap device comprising: a body having a proximal end, a distal opening, and a cavity extending therebetween (10), the cavity comprising an internal wall (9); a pad (12; Fig 5) seated within the cavity and contacting the proximal end, the pad having a distal surface that is compressible from a resting position to a compressed position (Fig 5 compared to Fig 3); and a set of threads (15; Fig 5) comprising a portion of the internal wall, the threads being configured to threadedly receive a patient fluid line access valve to a depth sufficient to

compress the pad from the resting position to the compressed position (Fig 5 compared to Fig 3). Further, with regard to claims 47, see 11 containing antibacterial agent, and wherein when in the configuration shown in Fig 3, the pad 12 absorbs the antibacterial agent after capsule 11 is broken. For claim 51, see Figs 3.

9. With regards to claim 61 and 67, Menyhay further discloses the pad holding a cleaning solution (see 11 containing antibacterial agent, and wherein when in the configuration shown in Fig 3, the pad 12 absorbs the antibacterial agent after capsule 11 is broken), and a proximal end or a portion of the thread being in contact with the pad (15, 12; Fig 3, 5). With regards to claims 37, 62-64, 66 see Figs 3 and 5. With regards to claim 65, see 11 containing antibacterial agent, and wherein when in the configuration shown in Fig 3, the pad 12 absorbs the antibacterial agent after capsule 11 is broken to become a "wet" pad.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menyhay in view of Busch (2004/0004019).

5. Menyhay discloses the invention substantially as claimed except for a removable lid over the open end of the housing to seal the cavity or an anti-microbial agent that includes at least one of chlorohexidine gluconate and chlorhexidine diacetate.

6. Busch teaches that it is known to have a removable lid (24) over the open end of a housing (12) and secured to a projecting flange of the housing (see lip on housing 12 in Figs 1-2) to seal the cavity and a pad (28) being a sponge having an antiseptic solution of chlorohexadine or chloridexadine gluiconate (¶26) for the purpose of maintaining the sterility of the device prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Menyhay with the flange and lid and antimicrobial agent as taught by Busch for the purpose of maintaining the sterility of the device prior to use.

7. Claim 34, 43, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menyhay in view of Velde et al (4778447). Menyhay discloses the invention substantially as claimed except for expressly disclosing the housing is formed of a polyethylene or polypropylene material. Velde et al teaches that it is known to have the housing formed of a polyethylene or polypropylene material (col 3, lns 43-57) for the purpose of providing an ultra-violet transparent material for the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cap material as taught by Menyhay in view of Busch with the polypropylene material as taught by Velde et al for the purpose of providing an ultra-violet transparent material for the cap.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M. Gilbert/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/281,711		Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW GILBERT		Art Unit 3767	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,554,135	09-1996	Menyhay, Steve Z.	604/256
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	11/20/2009	06/08/2010	04/04/2012	09/19/2012				
	1	✓	✓	✓	-				
	2	✓	-	-	-				
	3	✓	-	-	-				
	4	✓	✓	-	-				
	5	✓	-	-	-				
	6	✓	✓	-	-				
	7	✓	-	-	-				
	8	✓	✓	-	-				
	9	✓	✓	✓	-				
	10	✓	-	-	-				
	11	N	-	-	-				
	12	N	-	-	-				
	13	N	-	-	-				
	14	N	-	-	-				
	15	N	-	-	-				
	16	N	-	-	-				
	17	N	-	-	-				
	18	N	-	-	-				
	19	N	-	-	-				
	20	N	-	-	-				
	21		-	-	-				
	22		-	-	-				
	23		✓	✓	-				
	24		✓	-	-				
	25		✓	✓	-				
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	27		✓	✓	-				
	28		✓	-	-				
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	30		✓	-	-				
	31		✓	-	-				
	32		✓	-	-				
	33		✓	-	-				
	34		✓	✓	✓				
	35		✓	-	-				
	36		✓	-	-				

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant										☐ CPA										☐ T.D.										☐ R.1.47									
CLAIM		DATE																																					
Final	Original	11/20/2009	06/08/2010	04/04/2012	09/19/2012																																		
	37		✓	✓	✓																																		
	38		✓	-	-																																		
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	68					✓																																	

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

SEARCHED			
Class	Subclass	Date	Examiner
604	533, 265, 267	9/19/2012	AG

SEARCH NOTES			
Search Notes		Date	Examiner
Updated EAST class/subclass and keyword search done on 4/4/2012		9/19/2012	AG
Inventor Name and PLUS search		9/19/2012	AG
Forward/Backward citation searches		9/19/2012	AG

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW GILBERT/ Examiner.Art Unit 3767	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 01/23/2013 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 01/23/2013	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

<i>Applicant-Initiated Interview Summary</i>	Application No.	Applicant(s)	
	11/281,711	HOANG ET AL.	
	Examiner	Art Unit	
	ANDREW GILBERT	3767	

All participants (applicant, applicant's representative, PTO personnel):

(1) ANDREW GILBERT. (3) Craig Metcalf.

(2) David Conklin. (4) ____.

Date of Interview: 15 January 2013.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: ____.

Issues Discussed ☐ 101 ☒ 112 ☒ 102 ☐ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 61, 67 and 68.

Identification of prior art discussed: Menyhay (USPN 5554135).

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant and Examiner discussed the Final Rejection mailed on 9/25/2012 and the cited prior art of Menyhay in view of the applicant's claims. The applicant proposed claim amendments to distinguish the applicant's claimed invention over Menyhay, including reciting that the antimicrobial agent is impregnated or contained within the pad prior to attachment of the patient fluid line access valve. In contrast, Menyhay's antimicrobial agent is contained in a capsule, rather than the pad, prior to attachment of the patient fluid line access valve. Further, reciting that the body has a cavity comprising an internal wall having an inner circumference and a thread has a length that is approximately equal to the inner circumference. In contrast, Menyhay teaches a thread with a length equal to approximately 4-5 times the inner circumference, i.e. Fig 5 shows a thread 15 traversing the inner circumference 4-5 time. The applicant will file the amendments in a Request for Continued Examination and the Examiner will conduct a full search and consideration.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Andrew M. Gilbert/ Examiner, Art Unit 3767	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	11281711	Filing Date	2005-11-17	Docket Number (if applicable)	P-6836	Art Unit	3767
First Named Inventor	Minh Quang Hoang			Examiner Name	Andrew M. Gilbert		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
 Deposit Account No 500843

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2013-01-24
Name	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 11/281,711 Confirmation No.: 9168
Applicants : Minh Quang Hoang et al.
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Filed : November 17, 2005
TC/A.U. : 3767
Examiner : Andrew M. Gilbert
Docket No. : P-6836
Customer No. : 71562

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is being submitted in response to the Office Action mailed September 25, 2012 (the "Office Action"). Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed is:

1-68. (Canceled)

69. (New) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

 a housing having an opening to an inner cavity for receiving the access portion of the access valve;

 a wet pad holding a cleaning solution prior to receiving the access portion of the access valve;

 threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the access valve as the housing is placed over the access portion of the access valve to contact the wet pad with the face of the access portion of the access valve, and to disinfect the face and at least a portion of the external threads of the access portion of the access valve with the cleaning solution from the wet pad; and

 a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

70. (New) The device of claim 69, wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than or approximately equal to the inner circumference.

71. (New) The device of claim 69, wherein the threading threadedly receives the external threads thereby causing the interface to advance into the inner cavity such that the septum contacts the wet pad.

72. (New) The device of claim 69, wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

73. (New) The device of claim 72, wherein adjustable positioning of the septum within the cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.

74. (New) The device of claim 69, wherein the wet pad is a sponge.

75. (New) The device of claim 69, wherein the housing comprises a polyethylene or polypropylene material.

76. (New) The device of claim 69, wherein the cleaning solution comprises an antimicrobial agent.

77. (New) The device of claim 76, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

78. (New) The device of claim 76, wherein the cleaning solution is an alcohol-based cleaning solution.

79. (New) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing for covering the access portion of the access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the access valve;

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face of the access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity so that the end face of the access portion contacts the wet pad.

80. (New) The device of claim 79, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than or approximately equal to the inner circumference.

81. (New) The device of claim 79, wherein the cleaning solution comprises an antimicrobial agent.

82. (New) The device of claim 81, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

83. (New) The device of claim 81, wherein the cleaning solution is an alcohol-based cleaning solution.

84. (New) A device for maintaining a threaded patient fluid line access valve, the device comprising:

a housing having an inner cavity for covering an end face of the access valve;

a wet pad within the housing and impregnated with a cleaning solution prior to contacting the access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the access valve to reduce the amount of microbes on the access valve;

a thread within the inner cavity of the housing and positioned close to the wet pad for engaging the threaded patient fluid line access valve to contact the wet pad to the end face of the access valve; and

a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the end face of the access valve to be inserted into the housing and contact the wet pad.

85. (New) The device of claim 84, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than or approximately equal to the inner circumference.

86. (New) The device of claim 84, wherein the wet pad is a sponge.

87. (New) The device of claim 84, wherein the housing comprises a polyethylene or polypropylene material.

88. (New) The device of claim 84, wherein the cleaning solution is an alcohol-based cleaning solution.

REMARKS/ARGUMENTS

This paper is filed in response to the Office Action of September 25, 2012. In the Office Action, claims 34, 37, 43 and 61-67 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, claims 37, 47, 51, and 61-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Menyhay (US 5,554,143), claims 48 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Menyhay in view of Busch (US 2004/0004019), and claims 34, 43 and 49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Menyhay in view of Velde (US 4,778,447).

By this paper, claims 34-68 have been cancelled and new claims 69-88 have been added. Support for these new claims is found generally throughout the application, and specifically at page 8, lines 1-19, and Figure 10B. Accordingly, claims 69-88 are presented for consideration and/or immediate allowance by the Examiner.

Summary of Telephonic Interview

Applicants express appreciation to Examiner Gilbert for conducting a telephonic interview with Applicants' attorney on Tuesday, January 15, 2013. During the interview, Examiner Gilbert and Applicants' attorney discussed the application, the outstanding Office Action, and ways to overcome the prior art.

Rejections Under 35 U.S.C. §112, first paragraph

In the Office Action, the Examiner rejected claims 34, 37, 43, and 61-67 under 35 U.S.C. §112, first paragraph. Applicants have deleted these claims. Accordingly, Applicants request withdrawal of these rejections.

Rejections Under 35 U.S.C. §102(b) over Menyhay

In the Office Action, the Examiner rejected claims 37, 47, 51, and 61-68 as being anticipated by Menyhay. Under this section, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131 (*quoting Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Additionally, “the identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (*quoting Richardson v. Suzuki Motors, Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Furthermore, “the reference must be enabling and describe the applicant’s claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention.” *In re Paulsen*, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994).

Applicants submit that the new claims are not anticipated by Menyhay. In particular, Menyhay fails to teach or suggest “a wet pad holding a cleaning solution prior to receiving the access portion of the access valve.” *See* claim 69; *see also* claims 79 and 84. Rather, Menyhay teaches a “shatterable plastic capsule containing a combination of antiseptic, bactericidal and virucidal agents...[wherein]...as the screw threads of the present invention are tightened over the injection port...the pressure between the inwardly pointing projection and the capsule causes the capsule to break, releasing the antiseptic agents to be soaked up by the sponge.” *See* Menyhey at col. 4, lines 7-32.

Further, Menyhay fails to teach “a thread comprising a portion of the internal wall and having a length that is less than or approximately equal to the inner circumference [of the cavity]. *See* claims 70, 80 and 85, above. Rather, Menyhey teaches that the “helical screw

threads can be of any size that is small enough to allow at least two complete circuits, thereby assuring a tight seal.” *See* Menyhay at col. 7, lines 57-59. Menyhey further teaches that a plurality of helical threads 15 is desirable to retain sponge 12 in cylinder 10. *Id.* at Figure 3. Accordingly, the present claims are not anticipated by Menyhey. Applicants therefore request withdrawal of the present rejections.

Rejections Under 35 U.S.C. §103(a)

The Examiner has further rejected claims 34, 43, 48, 49 and 50 under 35 U.S.C. §103(a) as being unpatentable over various combinations of Menyhay, Busch and Velde. M.P.E.P. § 2141 sets forth the Graham factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Citing Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In addition, M.P.E.P. §§ 2141 and 2142 set forth that “the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” *Citing KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Accordingly, Applicants respectfully submit that 1) the references in the Office Action, either alone or in combination, do not teach or suggest all the limitations claimed in the amended claim set provided herein. Applicants also respectfully submits that 2) the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

Applicants submit that the new claims are patentable over the combined teachings of the cited prior art references. In particular, Applicants submit that the combined teachings of the

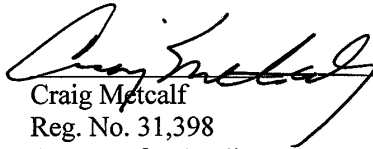
prior art references fail to teach “threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the access valve as the housing is placed over the access portion of the access valve to contact the wet pad with the face of the access portion of the access valve, and to disinfect the face and at least a portion of the external threads of the access portion of the access valve with the cleaning solution from the wet pad.” *See* claim 69, above. Further, the prior art references fail to teach “adjustable positioning of the septum within the inner cavity,” “wherein adjustable position of the septum within the cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.” *See* claims 72 and 73, above. Accordingly, applicants submit that the present invention is patentable over the combined teachings of Menyhay, Busch, and Velde. Applicants therefore request withdrawal of the present rejections.

Appl. No. 11/281,711
Amdt. dated January 24, 2013
Reply to Office Action of September 25, 2012

Conclusion

In light of the foregoing, Applicants respectfully submit that the claims as amended are in condition for immediate allowance. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is respectfully requested to call the undersigned.

Respectfully submitted,


Craig Metcalf
Reg. No. 31,398
Attorney for Applicant

Date: January 24, 2013

KIRTON | McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone: 801-328-3600

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		Lloyd Craig Metcalf/Kris Haley		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	1251	1	150	150

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for continued examination	1801	1	930	930
Total in USD (\$)				1080

Electronic Acknowledgement Receipt	
EFS ID:	14786342
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	24-JAN-2013
Filing Date:	17-NOV-2005
Time Stamp:	18:02:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1080
RAM confirmation Number	5670
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	P_6836_RCE_0124013.pdf	769562 d3e5d3f3aa3a889ac01a5d3f8ce2bfe6fb95c69c	no	3
Warnings:					
Information:					
2	Amendment Submitted/Entered with Filing of CPA/RCE	P_6836_OAResp_012413.pdf	353305 5a7abe375712d792de763de92bc7481101b352fd	no	10
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31938 2dc5746db2b2d0475aa0601f654e27424de9e102	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1154805		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed		
APPLICATION AS FILED – PART I											
(Column 1)			(Column 2)		SMALL ENTITY ☐		OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)			RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A				N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A				N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A				N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	OR		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.											
APPLICATION AS AMENDED – PART II										TOTAL	TOTAL
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	01/24/2013	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 20	Minus	** 27	= 0	X \$	=	OR		X \$62=	0
	Independent (37 CFR 1.16(n))	* 3	Minus	***6	= 0	X \$	=	OR		X \$250=	0
	☐ Application Size Fee (37 CFR 1.16(s))							OR			
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
						TOTAL ADD'L FEE			OR		TOTAL ADD'L FEE
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR		X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR		X \$	=
	☐ Application Size Fee (37 CFR 1.16(s))							OR			
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
						TOTAL ADD'L FEE			OR		TOTAL ADD'L FEE
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

Legal Instrument Examiner:
/ANTJUAN RIVERA/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6838	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5706944		1998-01-13	Hoang et al.	
	2	5547662		1996-08-20	Khan et al.	
	3	4626664		1986-12-02	Grise	
	4	4444310		1984-04-24	Odell	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20120039765	A1	2012-02-16	Solomon et al.	
	2	20100049170	A1	2010-02-25	Solomon et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711	
	Filing Date		2005-11-17	
	First Named Inventor	Minh Quang Hoang		
	Art Unit	3767		
	Examiner Name	Andrew M. Gilbert		
	Attorney Docket Number	P-6838		

	3	20100047123	A1	2010-02-25	Solomon et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. **Add**

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit		3767
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6838	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2013-04-16
Name/Print	Craig Metcalf	Registration Number	31,398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		Lloyd Craig Metcalf/Kris Haley		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt	
EFS ID:	15534631
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	16-APR-2013
Filing Date:	17-NOV-2005
Time Stamp:	18:12:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	5215
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P_6836_SupplIDS_041613.pdf	877841 8266babe145f59ff24162ff4e3fc2e450697227c	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	29926 5e01518d5cea8d50ecbb9324777a9e7ecb066da4	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			907767		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Office Action Summary	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3767	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 24 January 2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5) ☒ Claim(s) 69-88 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☒ Claim(s) 69-88 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☒ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 17 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some * c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/16/2013.

3) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 20130808.

4) ☐ Other: _____.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 08/15/2013 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 08/15/2013	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3767	

All participants (applicant, applicant's representative, PTO personnel):

(1) ANDREW GILBERT. (3) David Conklin.

(2) Craig Metcalf. (4) _____.

Date of Interview: 08 August 2013.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☒102 ☒103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 69-88.

Identification of prior art discussed: USPNs 4440207 and 5242425.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant and examiner discussed the claims filed with the RCE on 1/24/2013 in which the applicant filed new claims 69-88. The examiner noted several claims objections and 112 issues that are addressed in the attached office action. The applicant was suggested to amend the claims in a response accordingly to have consistent claim terminology throughout all claims. The applicant and examiner discussed a new matter objection for the recitation of the threading comprising a length approximately equal to the inner circumference and an objection to the specification for failing to provide proper antecedent basis for the threading having a length less than an inner circumference (see claims 70, 79, 84). No agreement was reached on the new matter issue. Further, the examiner discussed the Genatempo and White references as 103(a) rejections of the independent claims. The examiner and applicant discussed proposed claim language that would distinguish over the Genatempo and White references. Specifically, claim 69 requires the wet pad to disinfect the end face and at least a portion of the external threads of the access portion. The examiner strongly suggested incorporating this limitation into independent claims 79 and 84. Further, the applicant and examiner agreed that amending claim 69 with either of the following would distinguish claim 69 over Genatempo and White: (i) a distalmost end face having a first plane that includes a septum and the wet pad having a planar surface in a second plane being parallel to the first plane, wherein the distalmost end face contacts the planar surface of the access portion when the threads are engaged; and/or (ii) the threading being manually engaged with the external threads of the access portion before the end face and wet pad contact, wherein rotational movement of the threading with respect to the external threads causes the end face to advance into the inner cavity such that the septum comes into contact with the wet pad. No agreement was reached with regards to claim 69 or claims 79 and 84. The examiner will issue a Non-Final Rejection.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Andrew M. Gilbert/ Examiner, Art Unit 3767	

Summary of Record of Interview Requirements**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2013 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 1/24/2013.
3. In the reply, the applicant cancelled claims 34-68 and added new claims 69-88.
4. Thus, claims 69-88 are pending for examination.

Response to Arguments

5. Applicant's arguments with respect to the new claims 69-88 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

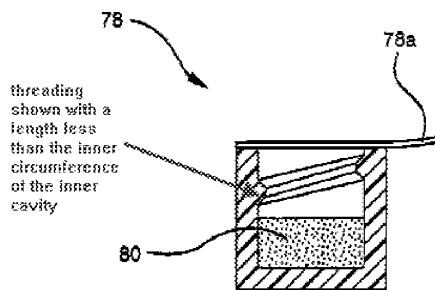
Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 4/16/2013 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide proper antecedent basis for the subject matter of: *"wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less ... than the inner circumference"* (claim 70, and see also similar claimed subject matter in claim 80 and 85). Fig 10B illustrates a threading with a length less than an inner circumference of the inner cavity of the housing. Thus, the new claimed subject matter has proper support and is not new matter. However, the specification fails to provide proper antecedent basis for the claimed subject matter and discuss the threading having a length less than the inner circumference.

FIG. 10B



Claim Objections

8. Claims 69, 79, and 84 are objected to because of the following informalities:

9. In the Applicant-Initiated Interview conducted on 8/8/2013, the applicant and examiner discussed amending the claims to recite consistent terminology throughout the claims. For example, claim 69 recites “a patient fluid line access valve”, “the access valve” and “the patient fluid line access valve”. The applicant agreed to amend the claims to recite “the patient fluid line access valve” instead of “the access valve” to be consistent.
10. In regards to claim 69, the term “the access valve” in Ins 4-5, 6-7, 9, 10, 11, and 12 should be changed to “the patient fluid line access valve”.
11. In regards to claim 79, the term “the access valve” in Ins 4, 6, 9, and 14 should be changed to “the patient fluid line access valve”.
12. In regards to claim 84, the term “the access valve” in Ins 3, 5, 6, 7, 9-10, 12, and 13 should be changed to “the threaded patient fluid line access valve”.
13. Appropriate correction is required.

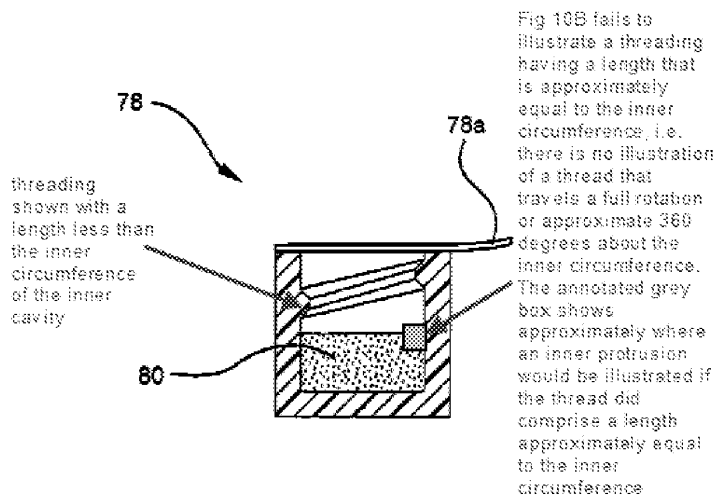
Claim Rejections - 35 USC § 112

14. The following is a quotation of 35 U.S.C. 112(a):
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
15. Claims 70, 80, and 85 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 70, 80, and 85 recite "*wherein the [inner cavity/cavity] comprises an inner circumference and the [threading/thread] comprises a length that is ... approximately equal to the inner circumference.*" This subject matter is not originally described. The applicant's original written specification and Figures fail to disclose and reasonably convey the subject matter of a length of the thread on the inner cavity being approximately equal to an inner circumference of the housing. Instead, the original disclosure only supports the thread on the inner cavity having a length less than the inner circumference of the inner cavity. Specifically, see annotated Fig 10B below and the annotated comments.

FIG. 10B



Art Unit: 3767

16. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 69, 71 and 73 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.
18. Claim 69 recites the limitation "the face" twice in ln 11. There is insufficient antecedent basis for this limitation in the claim. The recitation should read "the end face".
19. Claim 71 recites the limitation "the interface" in ln 2. There is insufficient antecedent basis for this limitation in the claim.
20. Claim 73 recites the limitation "the cavity" in 1-2. There is insufficient antecedent basis for this limitation in the claim. The recitation should read "the inner cavity".

Claim Rejections - 35 USC § 103

21. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter

of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

23. Claims 69, 72-74, 76 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Genatempo et al (4440207) in view of White et al (5242425).

24. With regards to claim 69, Genatempo et al discloses a device for maintaining a patient fluid line connector (Fig 1; 32; col 1, lns 6-13) having an access portion (tubular portion 40) with an end face (the examiner has interpreted the end face to be the exterior surface of the main tubular body 40 that contacts the wet pad 24 in Fig 3 (i.e. the exterior surface of 40 that is distal to the radial flange 36. The examiner notes that the term "end face" is broad enough to include an exterior surface of the connector and does not structurally require a planar surface or that the end face is solely the distalmost end of the structure. The examiner strongly suggests reciting the proposed limitations regarding the end face and wet pad listed in the attached Applicant Initiated Interview Summary form to distinguish the applicant's claimed invention over Genatempo et al) and external threads (42) on the access portion (tubular portion 40).

25. Further, Genatempo et al discloses the device comprising: a housing (10) having an opening (16) to an inner cavity (28) for receiving the access portion of the patient fluid line connector (Fig 3); a wet pad (24) holding a cleaning solution prior to receiving

the access portion of the patient fluid line connector (col 3, lns 23-25, 28-29, 40-45); threading (38) protruding inwardly into the inner cavity from an inner wall (30) of the housing near the opening (16), the threading to engage the external threads (42) of the access portion of the patient fluid line connector as the housing is placed over the access portion of the patient fluid line connector to contact the wet pad with the end face of the access portion of the patient fluid line connector (Fig 3), and to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line connector with the cleaning solution from the wet pad (Fig 3; col 3, lns 40-45; which states: "*The tube of absorbent material 24 is shown contacting main tubular portion 40 of connector 32. Preferably, absorbent material 24 retains an antiseptic or antibacterial agent. In this manner, an antibacterial effect is provided to main tubular member 40 of connector 32, as well as threads 42 through migration of the antiseptic.*" The examiner has interpreted this disclosure as a statement that during connection and engagement of the threads 38, 42 as illustrated in Fig 3, the end face (see above discussion of interpretation) will contact the wet pad 24 such that an antibacterial effect is provided to the end face of main tubular member 40. The examiner strongly suggests reciting the proposed limitations regarding the end face and wet pad listed in the attached Applicant Initiated Interview Summary form to distinguish the applicant's claimed invention over Genatempo et al).

26. Further, Genatempo et al discloses a removable lid (20) attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad

and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line connector (Fig 1; col 3, ln 1-5).

27. However, Genatempo et al does not expressly disclose that the patient fluid line connector is a patient fluid line access valve having an end face that includes a septum. White et al teaches that it is known to have a patient fluid line access valve (Fig 7) having an end face (planar end surface on the end of 86 that contacts 80 as shown in Fig 7) that includes a septum (84) for the purpose of providing a self-sealing septum valve closure that can be pierceable by a needle to delivery medicine or other liquid into the patient line and which also can be cleaned by an protective cap having an antiseptic material (col 2, lns 28-34; col 2, lns 59-61; col 7, lns 3-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the patient fluid line access connector as taught by Genatempo et al with the septum valve as taught by White et al for the purpose of providing a self-sealing septum valve closure that can be pierceable by a needle to delivery medicine or other liquid into the patient line and which also can be cleaned by an protective cap having an antiseptic material (col 2, lns 28-34; col 2, lns 59-61; col 7, lns 3-6).

28. Regarding claim 72, in a modified device of Genatempo et al in view of White et al as applied to claim 69 above, Genatempo et al further discloses wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity (interaction of the threads 38, 42 allows for rotation and adjustable positioning of the septum (positioned at the distal end of

tubular portion 40 of Genatempo et al as modified by White et al) within the inner cavity 28 of the housing 10).

29. Regarding claim 73, in a modified device of Genatempo et al in view of White et al as applied to claim 72 above, Genatempo et al further discloses wherein adjustable positioning of the septum within the cavity allows the septum to contact the wet pad (wherein the examiner notes that as modified in view of White et al, Genatempo et al will have a septum at the distalmost end of the tubular portion 40 to close the fluid lumen. The septum is allowed to contact the wet pad (24) before the threads (38, 42) are engaged by the user longitudinally inserting the connector 32 into the housing 10. The phrase “wherein adjustable positioning ... allows the septum to contact the wet pad” does not require that adjustable positioning of the septum by the threaded interaction results in contact of the septum and the wet pad. Rather, adjustable positioning can allow for positioning of the septum without the threaded interaction, i.e. when threads (38, 42) are not engaged, and this adjustable positioning can allow the septum to contact the wet pad (24). For example, this can occur during insertion of the distal end of the tubular portion (40) having the septum, as modified, into the inner cavity (28) allowing for contact to wet pad (24)).

30. Continuing with regards to claim 73, Genatempo et al further allows the septum to contact and compress the wet pad between the septum and the inner cavity (the examiner further notes that the current recitation does not require that adjustable positioning of the septum by the threaded interaction results in contact and compression of the septum and the wet pad. Rather, for example, when the threads (38, 42) are not

engaged, the septum on the distal end of the tubular portion (40) is fully capable, under movement by a user, of contacting and compressing the wet pad. This could be accomplished by moving the septum and distal end of the tubular portion (40) into the inner cavity at an angle so that the septum and distal end contact the wet pad (24) at an angle to compress the wet pad (24) into the side wall (26) of the housing. The examiner suggests reciting that the adjustable positioning is an adjustable positioning that results from relative movement of the threads during threaded interaction to distinguish the applicant's claimed invention over Genatempo et al in view of White et al.

31. Regarding claim 74, in a modified device of Genatempo et al in view of White et al as applied to claim 69 above, Genatempo et al further discloses wherein the wet pad is a sponge (24; see claim 11, stating the protective cap has an absorbent sponge carrying a liquid antiseptic).

32. Regarding claim 76, in a modified device of Genatempo et al in view of White et al as applied to claim 69 above, Genatempo et al further discloses wherein the cleaning solution comprises an antimicrobial agent (col 3, lns 41-43).

33. Claim 70 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Genatempo et al in view of White et al, as applied to claim 69 above, and in further view of Paradis (6117114). Genatempo et al in view of White et al discloses the invention substantially as claimed except for expressly disclosing the inner cavity threading comprises a length that is less than an inner circumference of the inner cavity. Paradis teaches that it is known to have a valve (Fig 1, 2a-2b, 3a-3b) having a threading having

a length that is less than an circumference of cylindrical connector (see partial Luer threads 43 as illustrated on cylindrical cap 40 in Fig 4a) for the purpose of providing an art recognized equivalent threaded luer connection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the threads (38, 42) having multiple helical rotations and lengths larger than the circumferences of the cylindrical chamber 30 and tubular portion 40, as taught by Genatempo et al in view of White et al, to be a partial thread with a length less than a circumference of a cylindrical connector taught by Paradis for the purpose of providing an art recognized equivalent threaded luer connection.

34. Claim 75 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Genatempo et al in view of White et al, as applied to claim 69 above, and in further view of Velde et al (4778447). Genatempo et al in view of White et al discloses the invention substantially as claimed, including that the housing is a polyester material, and that substantially equivalent materials can also be used (col 3, lns 23-25 of Genatempo et al) except for expressly disclosing the housing is formed of a polyethylene or polypropylene material. Velde et al teaches that it is known to have an female antiseptic cap housing (56a; Fig 18; col 7, lns 64-col 8, ln 2) formed of a polyethylene or polypropylene material (col 2, lns 48-50) for the purpose of providing a cap with a bacteriocidal connection, yet which made of a material transparent to ultra-violet radiation to also allow for UV-radiation disinfection or sterilization of the connection surfaces (col 1, lns 66-col 2, ln 2). It would have been obvious to one having ordinary

skill in the art at the time the invention was made to modify the cap material as taught by Genatempo et al in view of White et al with the polypropylene material as taught by Velde et al for the purpose of providing a cap with a bacteriocidal connection, yet which made of a material transparent to ultra-violet radiation to also allow for UV-radiation disinfection or sterilization of the connection surfaces (col 1, lns 66-col 2, lns 2).

35. Claims 77-78 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Genatempo et al in view of White et al, as applied to claim 76 above, and in further view of Busch (2004/0004019). Genatempo et al and White disclose the invention substantially as claimed except for the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate or is an alcohol-based cleaning solution. Busch teaches that it is known to have the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate (§26) or is an alcohol-based cleaning solution (§26; i.e. can have a 70% isopropyl alcohol base) for the purpose of providing an antiseptic cleaning solution with a quick drying time for maintaining and sterilizing a device/area (§26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cleaning solution as taught by Genatempo et al and White et al with the chlorhexidine gluconate or chlorhexidine diacetate or alcohol-based cleaning solution as taught by Busch for the purpose of providing an antiseptic cleaning solution with a quick drying time for maintaining and sterilizing the patient fluid line access valve (§26).

36. Claims 79, 81, 84, and 86 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over White et al (5242425) in view of Genatempo et al (4440207).

37. With regards to claim 79, White discloses a device (Fig 7) for maintaining a patient fluid line access valve (Fig 7; col 2, Ins 53-64) having an access portion (74, 86, 82) with an end face (84) that includes a septum (84) and external threads (74) on the access portion proximate the septum (Fig 7; where the examiner has interpreted "proximate" to mean "very near" and as shown in Fig 7 the external threads (74) are "very near" to the septum (84)), the device comprising: a housing (78; Fig 7) for covering the access portion of the access valve (Fig 7), the housing having an open end, a closed end, and a cavity (78 in Fig 7 shows a closed end, an open end with internal threads 76 and a cavity housing the sponge 80), the housing including a thread (76) on an inner wall of the cavity for engaging the external threads on the access portion of the access valve (Fig 7); a wet pad (80) impregnated with a cleaning solution (col 7, Ins 27-33) prior to attachment of the housing to the access portion of the patient fluid line access valve (wherein the examiner notes that the wet pad/sponge 80 necessarily must be saturated with antiseptic prior to attachment of the access portion to perform the disclosed function of bathing the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84 in antiseptic), the wet pad being positioned within the cavity (80 within 78 in Fig 7) for contacting the end face of the access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion (Fig 7; col 7, Ins

27-35; where Fig 7 shows the end face and the septum (84) contacting the wet pad/sponge 80).

38. However, White et al does not expressly disclose a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity. Genatempo et al teaches that it is known to have a lid (20; Fig 1) over the open end (16) of the housing (10) to seal the cavity with the wet pad within the cavity and provide a moisture barrier (col 2, lns 63-66; col 3, lns 1-5), the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity (col 2, lns 63-66; col 3, lns 1-5) for the purpose of preventing evaporation of the antibacterial agent from the absorbent wet pad before use (col 2, lns 63-66; col 3, lns 1-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the housing cleaner cap (78) as taught by White et al with the removable lid to expose the wet pad as taught by Genatempo et al for the purpose of preventing evaporation of the antibacterial agent from the absorbent wet pad before use (col 2, lns 63-66; col 3, lns 1-5).

39. Regarding claim 81, in a modified device of White et al in view of Genatempo et al as applied to claim 79 above, White et al further discloses the cleaning solution comprises an antimicrobial agent (col 7, lns 27-35; where an antiseptic is within the scope of an antimicrobial agent).

40. Regarding claim 84, White et al discloses a device (Fig 7) for maintaining a threaded patient fluid line access valve (Fig 7; col 2, lns 53-64; 74, 86, 82, with threads

74), the device comprising: a housing (78) having an inner cavity for covering an end face of the access valve (Fig 7); a wet pad (80) within the housing and impregnated with a cleaning solution prior to contacting the access valve (col 7, lns 27-33; wherein the examiner notes that the wet pad/sponge 80 necessarily must be saturated with antiseptic prior to attachment of the threaded valve with septum 84 to perform the disclosed function of bathing the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84 in antiseptic), the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the access valve to reduce the amount of microbes on the access valve (Fig 7; col 7, lns 27-35; where Fig 7 shows the end face and the septum (84) contacting the wet pad/sponge 80); a thread (76) within the inner cavity of the housing and positioned close to the wet pad for engaging the threaded patient fluid line access valve to contact the wet pad to the end face of the access valve (Fig 7; showing 74 and 76 engaged; where the examiner has interpreted as shown in Fig 7 the thread (76) is "close" to the wet pad (80)).

41. However, White et al does not expressly disclose a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the end face of the access valve to be inserted into the housing and contact the wet pad. Genatempo et al teaches that it is known to have a lid (20; Fig 1) providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve (col 2, lns 63-66; col 3, lns 1-5), the lid being removable to allow the end face of the access valve

to be inserted into the housing and contact the wet pad (col 2, lns 63-66; col 3, lns 1-5) for the purpose of preventing evaporation of the antibacterial agent from the absorbent wet pad before use (col 2, lns 63-66; col 3, lns 1-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the housing cleaner cap (78) as taught by White et al with the removable lid to expose the wet pad as taught by Genatempo et al for the purpose of preventing evaporation of the antibacterial agent from the absorbent wet pad before use (col 2, lns 63-66; col 3, lns 1-5).

42. Regarding claim 86, in a modified device of White et al in view of Genatempo et al as applied to claim 84 above, White et al further discloses the wet pad is a sponge (80; col 7, ln 28).

43. Claims 80 and 85 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over White et al in view of Genatempto et al, as applied to claim 79 and 84 respectively above, and in further view of Paradis (6117114). White et al in view of Genatempto et al discloses the invention substantially as claimed except for expressly disclosing the inner cavity threading comprises a length that is less than an inner circumference of the inner cavity. Paradis teaches that it is known to have a valve (Fig 1, 2a-2b, 3a-3b) having a threading having a length that is less than an circumference of cylindrical connector (see partial Luer threads 43 as illustrated on cylindrical cap 40 in Fig 4a) for the purpose of providing an art recognized equivalent threaded luer connection. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify the threads (74, 76) having multiple helical rotations and lengths larger than the circumferences of the cylindrical portions 78 and 82, as taught by White et al in view of Genatempto et al, to be a partial thread with a length less than a circumference of a cylindrical connector as taught by Paradis for the purpose of providing an art recognized equivalent threaded luer connection.

44. Claims 82-83, 88 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over White et al in view of Genatempto et al, as applied to claim 79 above for claims 82-83 and as applied to claim 84 above for claim 88, and in further view of Busch (2004/0004019). White et al in view of Genatempto et al disclose the invention substantially as claimed except for the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate or is an alcohol-based cleaning solution. Busch teaches that it is known to have the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate (§26) or is an alcohol-based cleaning solution (§26; i.e. can have a 70% isopropyl alcohol base) for the purpose of providing an antiseptic cleaning solution with a quick drying time for maintaining and sterilizing a device/area (§26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cleaning solution as taught by White et al in view of Genatempto et al with the chlorohexidine gluconate or chlorhexidine diacetate or alcohol-based cleaning solution as taught by Busch for the purpose of providing an antiseptic cleaning solution with a quick drying time for maintaining and sterilizing the patient fluid line access valve (§26).

45. Claim 87 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over White et al in view of Genatempto et al, as applied to claim 84 above, and in further view of Velde et al (4778447). White et al in view of Genatempto et al discloses the invention substantially as claimed, including that the housing is a polyester material and that substantially equivalent materials can also be used (col 3, Ins 23-25 of Genatempo et al), except for expressly disclosing the housing is formed of a polyethylene or polypropylene material. Velde et al teaches that it is known to have an female antiseptic cap housing (56a; Fig 18; col 7, Ins 64-col 8, Ins 2) formed of a polyethylene or polypropylene material (col 2, Ins 48-50) for the purpose of providing a cap with a bacteriocidal connection, yet which made of a material transparent to ultra-violet radiation to also allow for UV-radiation disinfection or sterilization of the connection surfaces (col 1, Ins 66-col 2, Ins 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cap material as taught by White et al in view of Genatempto et al with the polypropylene material as taught by Velde et al for the purpose of providing a cap with a bacteriocidal connection, yet which made of a material transparent to ultra-violet radiation to also allow for UV-radiation disinfection or sterilization of the connection surfaces (col 1, Ins 66-col 2, Ins 2).

Allowable Subject Matter

46. Claim 71 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest the subject matter of the threading on an inner cavity threadedly receives external threads on a housing thereby causing the interface (see 112 discussion above) to advance into the inner cavity such that the septum contacts the wet pad. Here, as discussed in the attached Applicant-Initiated Interview Summary form, the threading being manually engaged with the external threads of the access portion before the end face and wet pad contact and the rotational interaction of the threading causing the end face and septum to advance into the inner cavity such that the septum then contacts the wet pad, in combination with the other elements of the claims, is not taught or suggested by the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M. Gilbert/
Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/281,711	Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3767	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,117,114	09-2000	Paradis, Joseph R.	604/246
*	B	US-5,242,425	09-1993	White et al.	604/256
*	C	US-4,440,207	04-1984	Genatempo et al.	150/154
*	D	US-4,778,447	10-1988	Velde et al.	604/29
*	E	US-2004/0004019	01-2004	Busch, L. John	206/571
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47				
CLAIM		DATE								
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	5	✓	-	-	-	-				
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	35		✓	-	-	-				
	36		✓	-	-	-				

Index of Claims 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47				
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	71					✓				
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<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE													
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	86					✓									
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	88					✓									

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	128	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$ or US-20040004019-\$).did. or (US-20060039742-\$ or US-20080021392-\$ or US-20080021381-\$ or US-20080107564-\$ or US-20090024096-\$ or US-20090041619-\$ or US-20090297400-\$ or US-20100049170-\$ or US-20100047123-\$ or US-20100064456-\$ or US-20100100056-\$ or US-20100242993-\$ or US-20100286637-\$ or US-20100292673-\$ or US-20100296968-\$ or US-20110054440-\$ or US-20110150958-\$ or US-20110184382-\$ or US-20110236258-\$ or US-20110314619-\$ or US-20120039765-\$ or US-20010016589-\$ or US-20030162839-\$ or US-20080075761-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/08 20:13

		4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$ or US-7704935-\$ or US-7866907-\$ or US-8113731-\$ or US-6488942-\$ or US-6846846-\$ or US-8167847-\$ or US-8206514-\$ or US-8252247-\$ or US-8388894-\$ or US-4610469-\$ or US-3595419-\$ or US-4800904-\$ or US-7857793-\$).did. or (US-2961682-\$ or US-0877946-\$).did. or (US-20080086091-\$).did.				
L4	0	2 and (partial half) near2 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
L5	0	2 and (partial half quarter length) near2 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
L6	6	2 and (partial half quarter length) with thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
L7	2605	(cap connector) with (partial half quarter length) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
L8	918	(cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
L9	68	valve same (cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
L10	6	medical and valve same (cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
L11	9	valve same (cap connector) with (partial half quarter) near3 thread\$3 with inner	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:22
S1	56	((MINH) near2 (HOANG)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:29
S2	16	((JONATHAN) near2 (BURKHOLZ)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:30
S3	2	"US 20070112333"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2009/11/20 13:30
S4	0	("2007/0112333").URPN.	USPAT	OR	ON	2009/11/20 13:30
S5	1	2007-373158.NRAN.	DERWENT	OR	ON	2009/11/20 13:31
S6	9	("20060024372" "5763412" "6617294" "6299610" "6350251" "6482197" "6592564" "6679870" "6685694").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:51

S7	803	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S8	766	(604/265).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S9	124	(604/267).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S10	237	(S7 S8 S9) and (antiseptic\$4 clean\$4 antimicrobial antibacterial) and valve	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:54
S11	107	S10 and connector	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S12	16	S10 and pad	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S13	32	("20020066702" "20020091424" "20020123787" "20020193752" "20040116845" "20050038376" "20050038376" "20050095351" "20050256500" "4765588" "5251873" "5260020" "5295657" "5295658" "5312813" "5342316" "5441487" "5474544" "5501426" "5533708" "5549651" "5957898" "6171287" "6261282" "6282444" "6344033" "6428491" "6562295" "6595964" "6651956" "6669681" "6866656" "6908459").FN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:01
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S17	50	("5531341" "4326569" "5203771" "20070112333" "20070176117" "6027492" "4375849" "4867309" "5913631" "6245056" "20030233074" "5401239" "5505695" "6206854" "4293898" "4324516" "4368737" "4368730" "4384590" "4392326" "4405313" "4407429" "4417888" "4453636" "4465200" "4484595" "4496349" "4503560" "4513888" "4537273" "4538564" "4546944"	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:08

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S18	62	(S13 S15 S16 S17) and (antiseptic\$4 clean\$4 antimicrobial antibacterial steriliz\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:11
S19	13	((("4354490") or ("4432764") or ("4440207") or ("4655762") or ("4778447") or ("5554135") or ("5334388") or ("5792120") or ("6045539") or ("20070202177") or ("20080027399") or ("20080177250") or ("20090149819"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 14:27
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S21	46	("2999260" "20020197738" "20050115856" "20050124709" "20070093762" "20070112333" "20080011310" "20080086091" "20080177250" "20090008393" "20090028750" "20090041619" "20090062766" "3103029" "3183543" "3240326" "3450129" "3903345" "3915806" "3945380" "3039938" "3450129" "4243035" "4440207" "4725267" "5088146" "5372429" "5533708" "5190534" "5433705" "5554135" "5820955" "6753306" "6045539" "6423550" "6677258" "6893428" "7127771" "7214214" "7316669" "D342134").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:47
S22	5	("20060048313" "20070225660" "20080132880" "4862549" "6745425").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:51
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S24	7	("20050013836" "4317446" "4440207" "5827244" "6045539" "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:00
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S28	45	("1595350" "2961682" "20040258560" "20050147524" "20050214185" "20050222542" "20060030827" "3447161" "4282891" "4354490" "4431424" "4432759" "4440207" "4517702" "4551146" "4655762" "4671306" "4810241" "0490682" "5006114" "5163375" "5201725" "5242425" "5242432" "5274874" "5340359" "5554135" "5639310" "5676346" "5694978" "5743892" "5782808" "5792120" "5925191" "6045539" "6669681" "6708363" "6810552" "7083605" "0860088").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:16
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S35	8	("D176310").URPN.	USPAT	OR	ON	2010/06/08 10:48
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S38	22	((("7452349") or ("7083605") or ("6911025") or ("4624664") or ("5195957") or ("7682561") or ("4432764") or ("20030153865") or ("7198611") or ("6994315") or ("2961682") or ("4282891") or ("4671306") or ("4778447") or ("20050124970") or ("20060030827") or ("20070225660") or ("5242425") or ("5694978") or ("6708363") or ("20040258560"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/06/08 11:20
S39	0	S38 and chlorhexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:18
S40	1	S38 and chlorhexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S41	0	S38 and (diacetate gluconate)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S42	6	S38 and (polyethylene polypropylene)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S43	2	S38 and polyester	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S44	69	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070202177" "20070225660" "20080027399" "20080177250" "20090149819" "4282891" "4354490" "4432764" "4440207" "4624664" "4655762" "4671306" "4778447" "5195957" "5242425" "5334388" "5554135" "5694978" "5792120" "6045539" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2010/09/09 10:00
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S46	22	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664"	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:24

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S47	88	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$).did. or (US-2961682-\$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:35
S48	7	S47 and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S49	7	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S50	14	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41

S51	7	S50 not S49	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S52	22	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664" "4671306" "4778447" "5195957" "5242425" "5694978" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S53	88	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$).did. or (US-2961682-\$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S54	14	(S52 S53) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S55	22	("2961682" "20030153865"	US-PGPUB;	OR	ON	2012/04/05

		"20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664" "4671306" "4778447" "5195957" "5242425" "5694978" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	USPAT; USOCR			10:35
S56	160	medical and connector and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:44
S57	26	("20010016589" "20020144705" "20030072781" "20030162839" "20040039349" "20060165751" "20060239954" "20080075761" "20080182921" "4584192" "4716032" "4915934" "4925668" "5023082" "5512199" "5547662" "5616338" "5861440" "6051609" "6337357" "6413539" "6488942" "6846846" "6861060" "7198800" "7268165").PN. OR ("7704935").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:55
S58	3	((("4440207") or ("4778447") or ("5242425"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/04/05 11:01
S59	22	("2007/0112333").URPN.	USPAT	OR	ON	2012/09/19 13:58
S60	1	("5554135").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/19 14:25
S61	24	("4335756" "4402691" "4432766" "4440207" "4507111" "5190534" "D342134").PN. OR ("5554135").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/09/19 14:25
S62	3	((("5554135") or ("20040004019") or ("4778447"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 10:30
S63	65	("7780794" "D607325" "20070167910" "7731679" "7776011" "20070249996" "4432764" "4728321" "4983161" "7431712" "7922701" "5554135" "20070282280" "7749189" "4243035" "4440207" "20070112333" "4507111" "7753891" "3977401" "5827244" "6045539" "4402691" "20090012426" "20040258560" "20050147524" "4778447" "20050013836" "4335756" "4432766" "20090093757" "7635344" "7799010" "7857793" "4417890" "4957637" "20050203460" "4624664" "20070265578" "6126640" "20060030827" "20100160894" "4703762" "4811847" "5989229" "6116468" "0877946" "4439184" "20070249966" "7731678" "7763006" "3270743" "5954957" "5820604" "20050065479" "4317446" "20090099529" "5190534" "5792120" "4041934" "4799926" "20110290799" "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/15 10:49
S64	8	"US 8167847"	US-PGPUB;	OR	ON	2013/01/15

			USPAT; USOCR; DERWENT			10:49
S65	1	("4440207").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 11:48
S66	32	("2007/0112333").URPN.	USPAT	OR	ON	2013/08/07 15:27
S67	1	("20060048313").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 15:37
S68	8	("4624664").PN. ("20050013836" "4317446" "4440207" "5827244" "6045539" "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:40
S69	15	("20050124970" "20080038167" "3987930" "4354490" "4440207" "4450624" "4778447" "4838875" "5951519" "6045539").PN. ("2351804" "4402691" "5792120").PN. ("4346703").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:49
S70	2	"US 20080177250"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 15:50
S71	3	("20050065479" "4440207" "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:58
S72	4	("20020168530" "20080107564" "20090137969" "20090297400").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:59
S73	2	("20030217423" "20060030827").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:06
S74	12	("20050038397" "20080132880" "20080190485" "20100063482" "5439451" "5492147" "5536258" "5738663" "6932795" "7014169" "7762524" "7922701").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:08
S75	2	((("4402691") or ("4440207"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:10
S76	3	("20070112333" "20100172794" "5554135").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:16
S77	3	("20110054440" "4667837" "7762988").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:17
S78	0	("8491546").URPN.	USPAT	OR	ON	2013/08/07 16:19
S79	4	("20100047123" "20100049170" "20120039765" "4444310" "4626664" "5547662" "5706944").PN.	USPAT	OR	ON	2013/08/07 16:20
S80	7	("20100047123" "20100049170" "20120039765" "4444310" "4626664" "5547662" "5706944").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:21
S81	124	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US- 20080027399-\$ or US-20080177250-\$ or	US-PGPUB; USPAT; USOCR;	OR	ON	2013/08/07 16:22

US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$ or US-20040004019-\$.did. or (US-20060039742-\$ or US-20080021392-\$ or US-20080021381-\$ or US-20080107564-\$ or US-20090024096-\$ or US-20090041619-\$ or US-20090297400-\$ or US-20100049170-\$ or US-20100047123-\$ or US-20100064456-\$ or US-20100100056-\$ or US-20100242993-\$ or US-20100286637-\$ or US-20100292673-\$ or US-20100296968-\$ or US-20110054440-\$ or US-20110150958-\$ or US-20110184382-\$ or US-20110236258-\$ or US-20110314619-\$ or US-20120039765-\$ or US-20010016589-\$ or US-20030162839-\$ or US-20080075761-\$.did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$.did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$.did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$ or US-7704935-\$ or US-7866907-\$ or US-8113731-\$ or US-6488942-\$ or US-6846846-\$ or US-8167847-\$ or US-8206514-\$ or US-8252247-\$ or US-8388894-\$.did. or (US-2961682-\$ or US-0877946-\$.did. or (US-20080086091-	DERWENT

		\$).did.				
S82	66	S81 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:22
S83	56	("2436291" "2596725" "2629124" "2673362" "2713693" "2722719" "2774093" "3316922" "3369553" "3375538" "4117566").PN. OR ("4282891").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:23
S84	87	("3396727" "4232677" "4273247" "4306976" "4340052" "4354490" "4403992").PN. OR ("4440207").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:29
S85	46	("4346703" "4417890" "4431424" "4432764" "4439188" "4440207" "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:32
S86	83	("3502097" "4346703" "4417890" "4440207" "4559043" "4610469" "4752292" "4781693" "4919658" "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:35
S87	44	("3557989" "3595419" "3612320" "3715063" "3973690" "4019646" "4210251" "4394923" "4597758" "5014869" "5060813").PN. OR ("5694978").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:37
S88	8	("6446659" "4874377" "RE33971" "5122123" "5733503" "5139483" "5047021" "4614514").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:47
S89	1	("4610469").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:51
S90	195	("3986508" "4022205" "4030494" "4143853" "4161949" "4334551" "4431424" "4508367" "4511359").PN. OR ("4610469").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:52
S91	60	("1152286" "1282679" "20030105452" "20030153865" "20030229312" "20040215170" "20050017380" "20060270990" "20070106205" "20080095680" "2582109" "3160327" "3458080" "4334551" "4346703" "4432764" "4440207" "4551146" "4573983" "4624664" "4642091" "4810241" "4919658" "4921491" "4983161" "5053003" "5056464" "5195957" "5301849" "5332113" "5435358" "5531810" "5536258" "5554135" "5792120" "5875942" "5894015" "5921425" "5971965" "6045539" "6113068" "6207201" "6299131" "6648158" "6706022" "6732876" "6875205" "7100890" "7198611" "7232419").PN. OR ("7682561").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:53
S92	270	(S83 S84 S85 S86 S87 S90 S91) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:54
S93	1774	(fluid and valve and (medical patient) and thread and (pad sponge foam swab) and (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2013/08/07 19:39

			EPO; JPO; DERWENT; IBM_TDB			
S94	6	((fluid and valve and (medical patient) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:40
S95	121	((cap cover) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:42
S96	23	((medical patient user) with (port valve connector connection) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:45
S97	109	((medical patient user) with (port valve connector connection) same (thread threading) same (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:46
S98	42	((medical patient user) same (cap cover) same (thread threading) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S99	1011	((medical patient user) same (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S100	103	((medical patient user) same (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid) with (pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:50
S101	125	(valve and (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S102	99	S101 not S100	US-PGPUB; USPAT;	OR	ON	2013/08/07 19:51

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S103	129	((fluid patient) with (line tube tubing) with (valve port connector luer) and (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:53
S104	0	(luer near3 (clean\$3 steriliz\$3 disinfect\$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S105	49	(luer near3 (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S106	12	((("4232677") or ("4610469") or ("4624664") or ("4440207") or ("4432764") or ("4778447") or ("5242425") or ("5694978") or ("6911025") or ("20060030827") or ("5554135") or ("20040004019")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 20:33
S107	18	("20040004019" "20050124970" "4440207" "4626664" "4778447" "5242425" "5547662" "5706944" "6911025" "6994315").PN. ("4444310" "5554135").PN. ("20080177250" "20090062766" "20090149819" "20100047123" "20100049170" "20120039765").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 20:45
S109	1148	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S110	156	(604/534).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S111	312	(604/535).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S112	45	(604/536).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S113	337	(604/537).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S114	190	(15/104.03).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:40
S115	797	(15/104.04).CCLS.	US-PGPUB; USPAT;	OR	OFF	2013/08/08 14:41

EAST Search History

			USOCR			
S116	398	(15/104.062).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S117	493	(15/104.92).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S118	941	(15/104.93).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S119	917	(15/104.94).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S120	2913	(422/28).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:46
S121	2	((("4440207") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 15:15

EAST Search History (Interference)

<This search history is empty>

8/ 8/ 2013 8:40:37 PM**C:\ Users\ agilbert\ Documents\ EAST\ Workspaces\ Workspaces\ 11281711.wsp**

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	533-537, 265, 267	8/8/2013	AG
15	104.03, 104.03, 104.062, 104.92, 104.93, 104.94	8/8/2013	AG
422	28	8/8/2013	AG

SEARCH NOTES		
Search Notes	Date	Examiner
Updated EAST class/subclass and keyword search done on 9/19/2012 - see attached sheets	8/8/2013	AG
Inventor Name and PLUS search	8/8/2013	AG
Forward/Backward citation searches	8/8/2013	AG
Consultation with Examiner Emily Schmidt	8/9/2013	AG

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/ANDREW GILBERT/ Examiner.Art Unit 3767	

Receipt date: 04/16/2013

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

11281711 - GALL: 3767

Approved for use through 07/31/2012. OMB 0851-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6838	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5706944		1998-01-13	Hoang et al.	
	2	5547662		1996-08-20	Khan et al.	
	3	4626664		1986-12-02	Grise	
	4	4444310		1984-04-24	Odell	
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20120039765	A1	2012-02-16	Solomon et al.	
	2	20100049170	A1	2010-02-25	Solomon et al.	

Receipt date: 04/16/2013 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711	11281711 - GAU: 3767
	Filing Date		2005-11-17	
	First Named Inventor	Minh Quang Hoang		
	Art Unit	3767		
	Examiner Name	Andrew M. Gilbert		
	Attorney Docket Number	P-6838		

	3	20100047123	A1	2010-02-25	Solomon et al.		
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Examiner Signature		/Andrew Gilbert/			Date Considered		08/08/2013
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.							

Receipt date: 04/16/2013 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711 11281711 - GAU: 3767
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6838	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2013-04-16
Name/Print	Craig Metcalf	Registration Number	31,398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 11/281,711 Confirmation No.: 9168
Applicants : Minh Quang Hoang et al.
Title : PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER
Filed : November 17, 2005
TC/A.U. : 3767
Examiner : Andrew M. Gilbert
Docket No. : P-6836
Customer No. : 71562

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is being submitted in response to the Office Action mailed August 15, 2013 (the "Office Action"). Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Amendments to the Specification are reflected on page 6 of this paper.

Amendments to the Drawings are reflected on page 7 of the paper.

Remarks/Arguments begin on page 8 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed is:

1-68. (Previously cancelled)

69. (Currently amended) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve;

a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve;

threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve, and to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad, wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad; and

a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

70. (Currently amended) The device of claim 69, wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than ~~or approximately equal to~~ the inner circumference.

71. (Cancelled)

72. (Previously presented) The device of claim 69, wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

73. (Currently amended) The device of claim 72, wherein adjustable positioning of the septum within the inner cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.

74. (Previously presented) The device of claim 69, wherein the wet pad is a sponge.

75. (Previously presented) The device of claim 69, wherein the housing comprises a polyethylene or polypropylene material.

76. (Previously presented) The device of claim 69, wherein the cleaning solution comprises an antimicrobial agent.

77. (Previously presented) The device of claim 76, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

78. (Previously presented) The device of claim 76, wherein the cleaning solution is an alcohol-based cleaning solution.

79. (Currently amended) A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve;

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion ~~to reduce the amount of microbes on the access portion~~; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad.

80. (Currently amended) The device of claim 79, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than ~~or approximately equal to~~ the inner circumference.

81. (Previously presented) The device of claim 79, wherein the cleaning solution comprises an antimicrobial agent.

82. (Previously presented) The device of claim 81, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

83. (Previously presented) The device of claim 81, wherein the cleaning solution is an alcohol-based cleaning solution.

84. (Currently amended) A device for maintaining a threaded patient fluid line access valve, the device comprising:

a housing having an inner cavity for covering an end face of the patient fluid line access valve;

a wet pad within the housing and impregnated with a cleaning solution prior to contacting the patient fluid line access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the threaded patient fluid line access valve to disinfect the end face and at least a portion of an external thread of ~~reduce the amount of microbes on the~~ threaded patient fluid line access valve;

a an internal thread within the inner cavity of the housing and positioned close to the wet pad for engaging the external thread of the threaded patient fluid line access valve, whereby rotational movement of the external thread with respect to the internal thread causes the end face to advance into the inner cavity such that a septum of the end face contacts ~~to contact~~ the wet pad ~~to the end face of the access valve~~; and

a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the threaded patient fluid line access valve, the lid being removable to allow the end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad.

85. (Currently amended) The device of claim 84, wherein the inner cavity comprises an inner circumference and the internal thread comprises a length that is less than ~~or approximately equal to~~ the inner circumference.

86. (Previously presented) The device of claim 84, wherein the wet pad is a sponge.

87. (Previously presented) The device of claim 84, wherein the housing comprises a polyethylene or polypropylene material.

88. (Previously presented) The device of claim 84, wherein the cleaning solution is an alcohol-based cleaning solution.

Amendment to the Specification

Please insert the following new paragraph after the existing paragraph [0044] of the
Published Patent Application:

Cap device 78 further comprises an inner circumference 82 that defines a cavity
in which pad 80 is housed. In some instances, cap device 78 comprises a thread
or threading 18 having a length that is less than inner circumference 82.

Amendment to the Drawings

Applicant has amended Figure 10B to include reference numbers 18 and 78, each having a reference line respectively indicating the threads or threading (18), and inner circumference (82) of cap device 78. A Replacement Sheet for this figure is included with this Response.

REMARKS/ARGUMENTS

This paper is filed in response to the Office Action of August 15, 2013. In the Office Action, the specification was objected to as failing to provide proper antecedent basis for the claimed subject matter, claims 69, 79 and 84 were objected to for various informalities, claims 70, 80 and 85 were rejected under 35 U.S.C. §112(a) as failing to comply with the written description requirement, claims 69, 71 and 73 were rejected under 35 U.S.C. §112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter which inventor regards as the invention, claims 69, 72-74 and 76 were rejected under 35 U.S.C. §103(a) as being unpatentable over Genatempo (4440207) in view of White (5242425), claim 70 was rejected under 35 U.S.C. §103(a) as being unpatentable over Genatempo in view of White, and in further view of Paradis (6117114), claim 75 was rejected under 35 U.S.C. §103(a) as being unpatentable over Genatempo in view of White, and in further view of Velde (4778447), claims 77-78 were rejected under 35 U.S.C. §103(a) as being unpatentable over Genatempo in view of White, and in further view of Busch (2004/0004019), claims 79, 81 and 84 were rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Genatempo, claims 80 and 85 were rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Genatempo, and in further view of Paradis, claims 82-83 and 88 were rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Genatempo, and in further view of Paradis, claims 82-83 and 88 were rejected under 35 U.S.C. 103(a) as being unpatentable over White in view of Genatempo, and in further view of Busch, and claim 87 was rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Genatempo, and in further view of Velde. The Office

further indicated that claim 71 would be allowable if rewritten to overcome all of the rejections, and include all of the limitations of the base claim.

By this paper, claims 69, 70, 73, 79, 80, 84 and 85 have been amended, claim 71 has been cancelled, and no new claims have been added. These amendments are largely provided in response to claim objections for various informalities. However, the amendments to claims 70, 80 and 85 are supported by the presently submitted amendments to the Specification and Figure 10B of the instant application. Further, support for the amendments to claims 69, 79 and 84 is found in paragraphs [0017-0019] and [0043-0049], and in Figures 1 and 10B. Accordingly, claims 69-70 and 72-88 are presented for reconsideration and/or immediate allowance by the Examiner.

Summary of Telephonic Interview

Applicant expresses appreciation to Examiner Gilbert for conducting a telephonic interview with Applicant's attorney on August 8, 2013. During the interview, Examiner Gilbert and Applicant's attorney discussed proposed claim language that could distinguish over the Genatempo and White references. Applicant has amended the instant claims to reflect the claim language and other recommendation made by Examiner Gilbert during the interview.

Objections to the Specification

In the Office Action, the Office objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Office stated the specification fails to provide proper antecedent basis for the subject matter of "wherein the inner cavity comprises an inner circumference and threading that comprises a length that is less than the inner

circumference” (*see* Office Action at page 3). The Office further states that “Fig 10B illustrates a threading with a length that is less than an inner circumference of the inner cavity of the housing” and thus “the new claimed subject matter has proper support and is not new matter” (*Id.*). Accordingly, Applicant has amended the specification to add a new paragraph which provides disclosure relating to “an inner circumference 82” and “a thread or threading 18 having a length that is less than inner circumference 82” (*see* Amendments to Specification on page 6 of this paper). Applicant has further amended Figure 10B to add reference numbers 18 and 82 with reference lines (*see* Amendment to the Drawings on page 7 of this paper; *see also* the Replacement Sheet, submitted herewith). Applicant therefore requests withdrawal of this objection.

Claim Objections

In the Office Action, the Office objected to claims 69, 79 and 84 for various informalities. Applicant has amended claims 69, 79 and 84 to overcome these objections. Applicant therefore requests that these objections be withdrawn.

Rejections Under 35 U.S.C. §112(a)

In the Office Action, the Examiner rejected claims 70, 80 and 85 under 35 U.S.C. §112(a). Applicant has amended these claims to remove the language “or approximately equal to” to overcome these rejections. Accordingly, Applicant requests that these rejections be withdrawn.

Rejections Under 35 U.S.C. §112(b)

The Office has further rejected claims 69, 71 and 73 under 35 U.S.C. §112(b). Applicant has amended these claims to provide proper antecedent basis for the limitations indicated by the Office. Applicant therefore requests that these rejections be withdrawn.

Rejections Under 35 U.S.C. §103(a)

The Examiner has further rejected claims 69, 70 and 72-88 under 35 U.S.C. §103(a) as being unpatentable over various combinations of Genatempo, White, Paradis, Busch and Velde. M.P.E.P. § 2141 sets forth the Graham factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Citing Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In addition, M.P.E.P. §§ 2141 and 2142 set forth that “the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” *Citing KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Accordingly, Applicant respectfully submits that 1) the references in the Office Action, either alone or in combination, do not teach or suggest all the limitations claimed in the amended claim set provided herein. Applicant also respectfully submits that 2) the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

Applicant submits that the claims, as presently amended, are patentable over the combined teachings of the cited prior art references. In the Office Action, the Office indicated that claim 71 would be allowable if rewritten to overcome the various rejections, and to include

all of the limitations of the base claim and any intervening claims. By this paper, Applicant has cancelled claim 71 and amended claim 69 to include the limitations of claim 71. Applicant has further amended the subject matter of claim 71 to overcome all of the objections and rejections made under 35 U.S.C. §112 (b). Accordingly, Applicant submits that claim 69 is now in condition for allowance. Further, Applicant submits that claims 70 and 72-78 are also in condition for allowance based at least upon their dependencies from claim 69. Applicant therefore request that the rejections for these claims be withdrawn.

Regarding independent claim 79, Applicant submits that this claim has been amended to include limitations that are not taught in the art of record. In particular, Applicant submits that the combined teachings of the prior art references fail to teach “a wet pad...positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve...” (*see* amended claim 79, above). Accordingly, Applicant submits that claim 79 is now in condition for allowance. Further, Applicant submits that claims 80-83 are also in condition for allowance based at least upon their dependencies from claim 79. Applicant therefore request that the rejections for these claims be withdrawn.

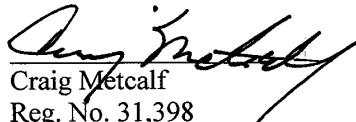
Further, regarding independent claim 84, Applicant submits that this claim has been amended to also include limitations that are not taught in the art of record. In particular, Applicant submits that the combined teachings of the prior art references fail to teach “an internal thread within the inner cavity of the housing and positioned close to the wet pad for engaging the external thread of the threaded patient fluid line access valve, whereby rotational movement of the external thread with respect to the internal thread causes the end face to

advance into the inner cavity such that a septum of the end face contact the wet pad...” (see amended claim 84, above). Accordingly, Applicant submits that claim 84 is now in condition for allowance. Further, Applicant submits that claims 85-88 are also in condition for allowance based at least upon their dependencies from claim 84. Applicant therefore requests that the rejections for these claims be withdrawn.

Conclusion

In light of the foregoing, Applicant respectfully submits that the claims as amended are in condition for immediate allowance. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is respectfully requested to call the undersigned.

Respectfully submitted,


Craig Metcalf
Reg. No. 31,398
Attorney for Applicant

Date: November 14, 2013

KIRTON | McCONKIE
50 East South Temple
Salt Lake City, Utah 84111
Telephone: 801-328-3600

FIG. 10A

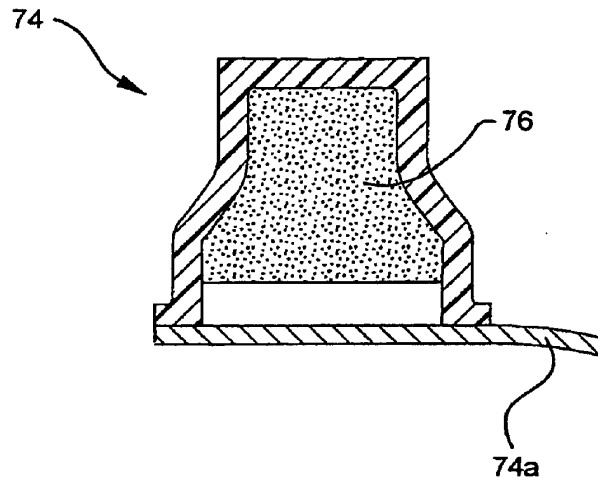
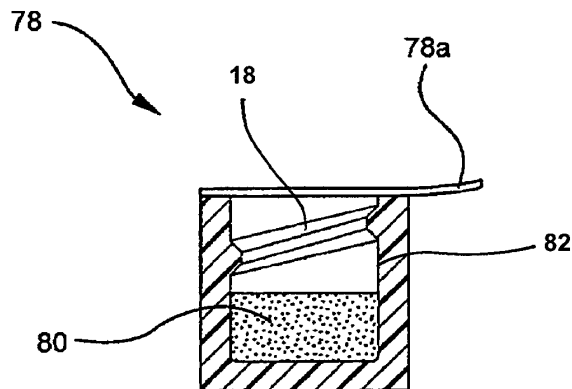


FIG. 10B



Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0851-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6227391	B1	2001-05-08	King	
	2	6116468		2000-09-12	Nilson	
	3	5954957		1999-09-21	Chin-Loy et al.	
	4	4991629		1991-02-12	Ernesto et al.	
	5	4671306		1987-06-09	Spector	
	6	4280632		1981-07-28	Yuhara	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711	
	Filing Date		2005-11-17	
	First Named Inventor	Minh Quang Hoang		
	Art Unit	3767		
	Examiner Name	Andrew M. Gilbert		
	Attorney Docket Number	P-6836		

	1	20050147524	A1	2005-07-07	Bousquet	

If you wish to add additional U.S. Published Application citation information please click the Add button. **Add**

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS				Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.		T ⁵
	1			☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit		3767
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2013-11-14
Name/Print	Craig Metcalf	Registration Number	31,398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		Lloyd Craig Metcalf/Kris Haley		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt	
EFS ID:	17407389
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	14-NOV-2013
Filing Date:	17-NOV-2005
Time Stamp:	17:39:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	4991
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P_6836_OAResp_111413.pdf	488308	yes	14
			7232116a1fde09bac0bed0a35eed736047f8938		
	Multipart Description/PDF files in .zip description				
	Document Description		Start		End
	Amendment/Req. Reconsideration-After Non-Final Reject		1		1
	Claims		2		5
	Specification		6		7
	Applicant Arguments/Remarks Made in an Amendment		8		13
	Drawings-only black and white line drawings		14		14
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	P_6836_SupplIDS_111413.pdf	896689	no	4
			807d0966ccf35e8633918e99eb6db58fbcb e77b5		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	29926	no	2
			87d1dc9e6becba2aca8b0a7a61cf8de785352c25		
Warnings:					
Information:					
Total Files Size (in bytes):			1414923		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 11/281,711		Filing Date 11/17/2005		☐ To be Mailed	

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA			RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*			X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*			X \$ =				
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))			If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.					TOTAL				

APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	11/14/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 19	Minus	** 27	= 0	x \$80 =	0		
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x \$420 =	0		
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		0	
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

71562 7590 01/21/2014
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/21/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168

TITLE OF INVENTION: Patient fluid line access valve antimicrobial cap/cleaner

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	04/21/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

71562 7590 01/21/2014
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168

TITLE OF INVENTION: Patient fluid line access valve antimicrobial cap/cleaner

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	04/21/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
GILBERT, ANDREW M	3763	604-533000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168

71562	7590	01/21/2014
David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirton & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880		

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/21/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1310 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1310 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 11/281,711	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the reply filed on 11/14/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 69,70 and 72-88. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>11/14/2013</u>	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	7. ☐ Other _____.
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date <u>20140113</u> .	

/ANDREW GILBERT/ Examiner, Art Unit 3763	/KEVIN C. SIRMONS/ Supervisory Patent Examiner, Art Unit 3763

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Acknowledgments

2. This office action is in response to the reply filed on 11/14/2013.
3. In the reply, the applicant amended claims 69, 70, 73, 79, 80, 84, and 85 and cancelled claim 71.
4. The applicant filed amendments to the Specification and a replacement drawing sheet that have been accepted.
5. Thus, claims 69-70, 72-88 are pending for examination.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 11/14/2013 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Craig Metcalf on 1/13/2014.

The application has been amended as follows:

In claim 84, In 3-4 the phrase "the patient fluid line access valve" has been changed to --the threaded patient fluid line access valve--.

In claim 84, In 5 the phrase "the patient fluid line access valve" has been changed to --the threaded patient fluid line access valve--.

ALLOWANCE

8. Claims 69-70, 72-88 are allowed.

9. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The prior art does not disclose or render obvious the combination as claimed specifically including housing having a wet pad positioned within a cavity having an internal thread, where the wet pad contacts the end face of an externally threaded patient fluid line access valve when the housing is positioned over and covers the access valve and rotational movement of the threads relative to another causes the end face to advance into the cavity resulting in the end face contacts the wet pad such that both the end face and at least a portion of the external threads of the access valve are disinfected in combination with the other elements of the claims.

10. The closest prior art is Genatempo (4440207), which as discussed in the Non-Final office action teaches disinfecting at least a portion of the external threads,

however Genatempo fails to teach or suggest an access valve having an end face that contacts the wet pad and is advanced into the cavity via the engagement of the threads. Rather, in Genatempo, by the time the respective threads are engaged, the end face has past the wet pad and is no longer in contact.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ANDREW GILBERT/
Examiner, Art Unit 3763
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3763

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	11/281,711	HOANG ET AL.	
	Examiner	Art Unit	
	ANDREW GILBERT	3763	

All participants (applicant, applicant's representative, PTO personnel):

(1) ANDREW GILBERT. (3) ____.

(2) Craig Metcalf (Reg. No. 31,398). (4) ____.

Date of Interview: 13 January 2014.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: ____.

Issues Discussed ☐ 101 ☒ 112 ☐ 102 ☐ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 84.

Identification of prior art discussed: N/A.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant and Examiner discussed claim 84 and agreed to amend lns 3 and 5 to recite "the threaded patient fluid line access valve" instead of "the patient fluid line access valve" to obviate a 112 antecedent basis issue. The claims are in conditions for allowance and the examiner will issue a Notice of Allowability.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/ANDREW GILBERT/ Examiner, Art Unit 3763	

Receipt date: 11/14/2013

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

11281711 - GALL: 3763

Approved for use through 07/31/2012. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6227391	B1	2001-05-08	King	
	2	6116468		2000-09-12	Nilson	
	3	5954957		1999-09-21	Chin-Loy et al.	
	4	4991629		1991-02-12	Ernesto et al.	
	5	4671306		1987-06-09	Spector	
	6	4280632		1981-07-28	Yuhara	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

Receipt date: 11/14/2013 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711	11281711 - GAU: 3763
	Filing Date		2005-11-17	
	First Named Inventor	Minh Quang Hoang		
	Art Unit	3767		
	Examiner Name	Andrew M. Gilbert		
	Attorney Docket Number	P-6836		

	1	20050147524	A1	2005-07-07	Bousquet			
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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
	1							☐
If you wish to add additional non-patent literature document citation information please click the Add button Add								
EXAMINER SIGNATURE								
Examiner Signature		/Andrew Gilbert/			Date Considered	01/13/2014		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.								

Receipt date: 11/14/2013 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		11281711 11281711 - GAU: 3763
	Filing Date		2005-11-17
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3767	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2013-11-14
Name/Print	Craig Metcalf	Registration Number	31,398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE													
Final	Original	11/20/2009	06/08/2010	04/04/2012	09/19/2012	08/08/2013	01/13/2014								
	1	✓	✓	✓	-	-	-								
	2	✓	-	-	-	-	-								
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	33		✓	-	-	-	-								
	34		✓	✓	✓	-	-								
	35		✓	-	-	-	-								
	36		✓	-	-	-	-								

<i>Index of Claims</i> 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

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CLAIM		DATE													
Final	Original	11/20/2009	06/08/2010	04/04/2012	09/19/2012	08/08/2013	01/13/2014								
	37		✓	✓	✓	-	-								
	38		✓	-	-	-	-								
	39		✓	-	-	-	-								
	40		✓	-	-	-	-								
	41		✓	-	-	-	-								
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	68				✓	-	-								
	69					✓	=								
	70					✓	=								
	71					✓	-								
	72					✓	=								

Index of Claims 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	11/20/2009	06/08/2010	04/04/2012	09/19/2012	08/08/2013	01/13/2014			
	73					✓	=			
	74					✓	=			
	75					✓	=			
	76					✓	=			
	77					✓	=			
	78					✓	=			
	79					✓	=			
	80					✓	=			
	81					✓	=			
	82					✓	=			
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	84					✓	=			
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	87					✓	=			
	88					✓	=			

Search Notes 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW M GILBERT	Art Unit 3767

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	533-537, 265, 267	1/13/2014	AG
15	104.03, 104.03, 104.062, 104.92, 104.93, 104.94	1/13/2014	AG
422	28	1/13/2014	AG

SEARCH NOTES		
Search Notes	Date	Examiner
Updated EAST class/subclass and keyword search done on 8/8/13	1/13/2014	AG
Inventor Name and PLUS search	1/13/2014	AG
Forward/Backward citation searches	1/13/2014	AG
Consultation with Examiner Emily Schmidt	1/13/2014	AG
Updated search	1/13/2014	AG
Interference search of PGPubs - see attached sheets	1/13/2014	AG

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See above	1/13/2014	AG
	Interference search of PGPubs - see attached sheets	1/13/2014	AG

/ANDREW GILBERT/ Examiner.Art Unit 3763	

Issue Classification 	Application/Control No. 11281711	Applicant(s)/Patent Under Reexamination HOANG ET AL.
	Examiner ANDREW GILBERT	Art Unit 3763

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION									
CLASS			SUBCLASS			CLAIMED					NON-CLAIMED				
604			267			A	6	1	M	25 / 00 (2006.01.01)					
CROSS REFERENCE(S)						A	6	1	M	25 / 16 (2006.01.01)					
						A	6	1	M	25 / 18 (2006.01.01)					
						A	6	1	M	39 / 00 (2006.01.01)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					A	6	1	M	39 / 10 (2006.01.01)					
604	533					A	6	1	M	39 / 10 (2006.01.01)					

/ANDREW GILBERT/ Examiner, Art Unit 3763 (Assistant Examiner)	01/13/2014 (Date)	Total Claims Allowed: 19	
/KEVIN C SIRMONS/ Supervisory Patent Examiner, Art Unit 3763 (Primary Examiner)	01/13/2014 (Date)	O.G. Print Claim(s) 69	O.G. Print Figure 10A-10B

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	1	("8491546").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/01/13 13:08
L5	0	(fluid and (set line tube tubing) and valve and septum and threads and internal and external and (pad sponge foam) and (clean\$4 disinfect\$4 steriliz\$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
L6	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam) and (clean\$4 disinfect\$4 steriliz\$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
L7	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
L8	1	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
L9	2	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (clean\$4 steriliz\$4 disinfect\$4)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
S1	56	((MINH) near2 (HOANG)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:29
S2	16	((JONATHAN) near2 (BURKHOLZ)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:30
S3	2	"US 20070112333"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2009/11/20 13:30
S4	0	("2007/0112333").URPN.	USPAT	OR	ON	2009/11/20 13:30
S5	1	2007-373158.NRAN.	DERWENT	OR	ON	2009/11/20 13:31
S6	9	("20060024372" "5763412" "6617294" "6299610" "6350251" "6482197" "6592564" "6679870" "6685694").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:51
S7	803	(604/533).OCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S8	766	(604/265).OCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S9	124	(604/267).OCLS.	US-PGPUB; USPAT;	OR	OFF	2009/11/20 13:53

			USOCR			
S10	237	(S7 S8 S9) and (antiseptic\$4 clean\$4 antimicrobial antibacterial) and valve	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:54
S11	107	S10 and connector	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S12	16	S10 and pad	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S13	32	("20020066702" "20020091424" "20020123787" "20020193752" "20040116845" "20050038376" "20050038376" "20050095351" "20050256500" "4765588" "5251873" "5260020" "5295657" "5295658" "5312813" "5342316" "5441487" "5474544" "5501426" "5533708" "5549651" "5957898" "6171287" "6261282" "6282444" "6344033" "6428491" "6562295" "6595964" "6651956" "6669681" "6866656" "6908459").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:01
S14	0	("2008/0027399").URPN.	USPAT	OR	ON	2009/11/20 14:04
S15	20	("20050124970" "20070202177" "20070287989" "20070293818" "20070293822" "20080021381" "20080027399" "20080038167" "20080039803" "20080086091" "20080095680" "20080107564" "20080147047" "3987930" "4340052" "4354490" "4369781" "4402691" "4432764" "4432766" "4440207" "4450624" "4778447" "4838875" "5466219" "5554135" "5792120" "5951519" "6045539" "6171287" "7198611" "D547446" "D550355").PN.	USPAT	OR	ON	2009/11/20 14:05
S16	4	("20050222542" "20060286155" "4232677" "6089541").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:07
S17	50	("5531341" "4326569" "5203771" "20070112333" "20070176117" "6027492" "4375849" "4867309" "5913631" "6245056" "20030233074" "5401239" "5505695" "6206854" "4293898" "4324516" "4368737" "4368730" "4384590" "4392326" "4405313" "4407429" "4417888" "4453636" "4465200" "4484595" "4496349" "4503560" "4513888" "4537273" "4538564" "4546944" "4602654" "4763648" "4801029" "4846191" "4847597" "4920970" "4923059" "4957484" "4974280" "4981140" "4981230" "4988073" "5016799" "5018794" "5193525" "5202849" "5218736" "5267968").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:08
S18	62	(S13 S15 S16 S17) and (antiseptic\$4 clean\$4 antimicrobial antibacterial steriliz\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:11

S19	13	((("4354490") or ("4432764") or ("4440207") or ("4655762") or ("4778447") or ("5554135") or ("5334388") or ("5792120") or ("6045539") or ("20070202177") or ("20080027399") or ("20080177250") or ("20090149819"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 14:27
S20	23	("20050124970" "20080038167" "3987930" "4354490" "4440207" "4450624" "4778447" "4838875" "5951519" "6045539").PN. ("2351804" "4402691" "5792120").PN. ("20020093192" "20040201216" "20050266714" "20080132880" "4324239").PN. ("20020093192" "20040201216" "20050266714" "20080105704" "20080132880" "20080235888" "4324239" "7040598" "7316669").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:35
S21	46	("2999260" "20020197738" "20050115856" "20050124709" "20070093762" "20070112333" "20080011310" "20080086091" "20080177250" "20090008393" "20090028750" "20090041619" "20090062766" "3103029" "3183543" "3240326" "3450129" "3903345" "3915806" "3945380" "3039938" "3450129" "4243035" "4440207" "4725267" "5088146" "5372429" "5533708" "5190534" "5433705" "5554135" "5820955" "6753306" "6045539" "6423550" "6677258" "6893428" "7127771" "7214214" "7316669" "D342134").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:47
S22	5	("20060048313" "20070225660" "20080132880" "4862549" "6745425").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:51
S23	5	("20050222542" "20060286155" "20070112333" "4232677" "6089541").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:55
S24	7	("20050013836" "4317446" "4440207" "5827244" "6045539" "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:00
S25	28	("0124970" "0132880" "20080095680" "20080147047" "0201216" "0266714" "3987930" "4324239" "4369781" "4432764" "4450624" "4778447" "4838875" "5466219" "5554135" "5792120" "5951519" "6045539" "6171287" "7198611" "0093192" "D547446" "D550355").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:06
S26	3	("4417890" "4440207" "5620424").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:11
S27	71	("3416567" "3633586" "3880401" "3918450" "4162092" "4187846" "4209013" "4256106" "4294250" "4340052").PN. OR ("4417890").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:14
S28	45	("1595350" "2961682" "20040258560" "20050147524" "20050214185"	US-PGPUB; USPAT;	OR	ON	2010/06/08 10:16

		"20050222542" "20060030827" "3447161" "4282891" "4354490" "4431424" "4432759" "4440207" "4517702" "4551146" "4655762" "4671306" "4810241" "0490682" "5006114" "5163375" "5201725" "5242425" "5242432" "5274874" "5340359" "5554135" "5639310" "5676346" "5694978" "5743892" "5782808" "5792120" "5925191" "6045539" "6669681" "6708363" "6810552" "7083605" "0860088").PN.	USOCR			
S29	2	((("7682561") or ("6994315"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/06/08 10:20
S30	55	("1152286" "1282679" "20030105452" "20030153865" "20030229312" "20040215170" "20050017380" "20060270990" "20070106205" "20080095680" "2582109" "3160327" "3458080" "4334551" "4346703" "4432764" "4440207" "4551146" "4573983" "4624664" "4642091" "4810241" "4919658" "4921491" "4983161" "5053003" "5056464" "5195957" "5301849" "5332113" "5435358" "5531810" "5536258" "5554135" "5792120" "5875942" "5894015" "5921425" "5971965" "6045539" "6113068" "6207201" "6299131" "6648158" "6706022" "6732876" "6875205" "7100890" "7198611" "7232419").PN. OR ("7682561").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:23
S31	20	("4346703" "4417890" "4431424" "4432764" "4439188" "4440207" "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:27
S32	24	("2636644" "2727516" "4022206" "4417890" "4431424" "4432764" "4432766" "4439188" "4440207" "4551146" "4588402" "4624664" "4642091" "4738668" "4778447" "4983161" "5053003").PN. OR ("5195957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:34
S33	11	("3986508" "4511359" "4610469" "4878516" "5190534" "5195957" "5334188" "5423775" "5792120").PN. OR ("6911025").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:42
S34	28	("20010016962" "20030060781" "20040021000" "20050124970" "20060030827" "3971376" "4301567" "4624664" "5048547" "5375589" "6045539" "6086275" "6450810" "6602219" "6673031" "6813797" "6813798" "7198611" "D176310" "D214555" "D258762" "D305261" "D325443" "D527461" "RE39499").PN. OR ("D596308").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:48
S35	8	("D176310").URPN.	USPAT	OR	ON	2010/06/08 10:48
S36	17	("1951099" "1994206" "2088658"	US-PGPUB;	OR	ON	2010/06/08

		"2471303" "2501193" "3984656" "D176310").PN. OR ("D296239").URPN.	USPAT; USOCR			10:50
S37	40	("3502097" "4346703" "4417890" "4440207" "4559043" "4610469" "4752292" "4781693" "4919658" "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 11:06
S38	22	((("7452349") or ("7083605") or ("6911025") or ("4624664") or ("5195957") or ("7682561") or ("4432764") or ("20030153865") or ("7198611") or ("6994315") or ("2961682") or ("4282891") or ("4671306") or ("4778447") or ("20050124970") or ("20060030827") or ("20070225660") or ("5242425") or ("5694978") or ("6708363") or ("20040258560"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/06/08 11:20
S39	0	S38 and chlorohexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:18
S40	1	S38 and chlorhexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S41	0	S38 and (diacetate gluconate)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S42	6	S38 and (polyethylene polypropylene)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S43	2	S38 and polyester	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S44	69	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070202177" "20070225660" "20080027399" "20080177250" "20090149819" "4282891" "4354490" "4432764" "4440207" "4624664" "4655762" "4671306" "4778447" "5195957" "5242425" "5334388" "5554135" "5694978" "5792120" "6045539" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2010/09/09 10:00
S45	11	("2007/0112333").URPN.	USPAT	OR	ON	2012/04/04 15:07
S46	22	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664" "4671306" "4778447" "5195957" "5242425" "5694978" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:24
S47	88	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US- 20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:35

		20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$).did. or (US-2961682-\$).did.				
S48	7	S47 and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S49	7	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S50	14	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S51	7	S50 not S49	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S52	22	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664" "4671306" "4778447" "5195957"	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34

		"5242425" "5694978" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.				
S53	88	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$).did. or (US-2961682-\$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S54	14	(S52 S53) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S55	22	("2961682" "20030153865" "20040258560" "20050124970" "20060030827" "20070225660" "4282891" "4432764" "4624664" "4671306" "4778447" "5195957" "5242425" "5694978" "6708363" "6911025" "6994315" "7083605" "7198611" "7452349" "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:35
S56	160	medical and connector and (sponge	US-PGPUB;	OR	ON	2012/04/05

		polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	USPAT; USOCR			10:44
S57	26	("20010016589" "20020144705" "20030072781" "20030162839" "20040039349" "20060165751" "20060239954" "20080075761" "20080182921" "4584192" "4716032" "4915934" "4925668" "5023082" "5512199" "5547662" "5616338" "5861440" "6051609" "6337357" "6413539" "6488942" "6846846" "6861060" "7198800" "7268165").PN. OR ("7704935").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:55
S58	3	((("4440207") or ("4778447") or ("5242425"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/04/05 11:01
S59	22	("2007/0112333").URPN.	USPAT	OR	ON	2012/09/19 13:58
S60	1	("5554135").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/19 14:25
S61	24	("4335756" "4402691" "4432766" "4440207" "4507111" "5190534" "D342134").PN. OR ("5554135").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/09/19 14:25
S62	3	((("5554135") or ("20040004019") or ("4778447"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 10:30
S63	65	("7780794" "D607325" "20070167910" "7731679" "7776011" "20070249996" "4432764" "4728321" "4983161" "7431712" "7922701" "5554135" "20070282280" "7749189" "4243035" "4440207" "20070112333" "4507111" "7753891" "3977401" "5827244" "6045539" "4402691" "20090012426" "20040258560" "20050147524" "4778447" "20050013836" "4335756" "4432766" "20090093757" "7635344" "7799010" "7857793" "4417890" "4957637" "20050203460" "4624664" "20070265578" "6126640" "20060030827" "20100160894" "4703762" "4811847" "5989229" "6116468" "0877946" "4439184" "20070249966" "7731678" "7763006" "3270743" "5954957" "5820604" "20050065479" "4317446" "20090099529" "5190534" "5792120" "4041934" "4799926" "20110290799" "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/15 10:49
S64	8	"US 8167847"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/01/15 10:49
S65	1	("4440207").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 11:48
S66	32	("2007/0112333").URPN.	USPAT	OR	ON	2013/08/07

						15:27
S67	1	("20060048313").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 15:37
S68	8	("4624664").PN. ("20050013836" "4317446" "4440207" "5827244" "6045539" "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:40
S69	15	("20050124970" "20080038167" "3987930" "4354490" "4440207" "4450624" "4778447" "4838875" "5951519" "6045539").PN. ("2351804" "4402691" "5792120").PN. ("4346703").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:49
S70	2	"US 20080177250"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 15:50
S71	3	("20050065479" "4440207" "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:58
S72	4	("20020168530" "20080107564" "20090137969" "20090297400").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:59
S73	2	("20030217423" "20060030827").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:06
S74	12	("20050038397" "20080132880" "20080190485" "20100063482" "5439451" "5492147" "5536258" "5738663" "6932795" "7014169" "7762524" "7922701").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:08
S75	2	((("4402691") or ("4440207"))).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:10
S76	3	("20070112333" "20100172794" "5554135").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:16
S77	3	("20110054440" "4667837" "7762988").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:17
S78	0	("8491546").URPN.	USPAT	OR	ON	2013/08/07 16:19
S79	4	("20100047123" "20100049170" "20120039765" "4444310" "4626664" "5547662" "5706944").PN.	USPAT	OR	ON	2013/08/07 16:20
S80	7	("20100047123" "20100049170" "20120039765" "4444310" "4626664" "5547662" "5706944").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:21
S81	124	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US- 20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US- 20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US- 20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 16:22

		\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$ or US-20040004019-\$).did. or (US-20060039742-\$ or US-20080021392-\$ or US-20080021381-\$ or US-20080107564-\$ or US-20090024096-\$ or US-20090041619-\$ or US-20090297400-\$ or US-20100049170-\$ or US-20100047123-\$ or US-20100064456-\$ or US-20100100056-\$ or US-20100242993-\$ or US-20100286637-\$ or US-20100292673-\$ or US-20100296968-\$ or US-20110054440-\$ or US-20110150958-\$ or US-20110184382-\$ or US-20110236258-\$ or US-20110314619-\$ or US-20120039765-\$ or US-20010016589-\$ or US-20030162839-\$ or US-20080075761-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$ or US-7704935-\$ or US-7866907-\$ or US-8113731-\$ or US-6488942-\$ or US-6846846-\$ or US-8167847-\$ or US-8206514-\$ or US-8252247-\$ or US-8388894-\$).did. or (US-2961682-\$ or US-0877946-\$).did. or (US-20080086091-\$).did.				
S82	66	S81 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:22
S83	56	("2436291" "2596725" "2629124" "2673362" "2713693" "2722719" "2774093" "3316922" "3369553"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:23

		"3375538" "4117566").PN. OR ("4282891").URPN.				
S84	87	("3396727" "4232677" "4273247" "4306976" "4340052" "4354490" "4403992").PN. OR ("4440207").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:29
S85	46	("4346703" "4417890" "4431424" "4432764" "4439188" "4440207" "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:32
S86	83	("3502097" "4346703" "4417890" "4440207" "4559043" "4610469" "4752292" "4781693" "4919658" "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:35
S87	44	("3557989" "3595419" "3612320" "3715063" "3973690" "4019646" "4210251" "4394923" "4597758" "5014869" "5060813").PN. OR ("5694978").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:37
S88	8	("6446659" "4874377" "RE33971" "5122123" "5733503" "5139483" "5047021" "4614514").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:47
S89	1	("4610469").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:51
S90	195	("3986508" "4022205" "4030494" "4143853" "4161949" "4334551" "4431424" "4508367" "4511359").PN. OR ("4610469").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:52
S91	60	("1152286" "1282679" "20030105452" "20030153865" "20030229312" "20040215170" "20050017380" "20060270990" "20070106205" "20080095680" "2582109" "3160327" "3458080" "4334551" "4346703" "4432764" "4440207" "4551146" "4573983" "4624664" "4642091" "4810241" "4919658" "4921491" "4983161" "5053003" "5056464" "5195957" "5301849" "5332113" "5435358" "5531810" "5536258" "5554135" "5792120" "5875942" "5894015" "5921425" "5971965" "6045539" "6113068" "6207201" "6299131" "6648158" "6706022" "6732876" "6875205" "7100890" "7198611" "7232419").PN. OR ("7682561").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:53
S92	270	(S83 S84 S85 S86 S87 S90 S91) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:54
S93	1774	(fluid and valve and (medical patient) and thread and (pad sponge foam swab) and (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:39
S94	6	(fluid and valve and (medical patient) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2013/08/07 19:40

			EPO; JPO; DERWENT; IBM_TDB			
S95	121	((cap cover) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:42
S96	23	((medical patient user) with (port valve connector connection) and (thread threading) same (pad sponge foam swab) with (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:45
S97	109	((medical patient user) with (port valve connector connection) same (thread threading) same (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:46
S98	42	((medical patient user) same (cap cover) same (thread threading) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S99	1011	((medical patient user) same (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S100	103	((medical patient user) same (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid) with (pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:50
S101	125	(valve and (cap cover) same (clean\$3 steriliz\$3 disinfect\$3) with (solution liquid) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S102	99	S101 not S100	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S103	129	((fluid patient) with (line tube tubing) with (valve port connector luer) and (cap	US-PGPUB; USPAT;	OR	ON	2013/08/07 19:53

		cover) same (clean\$3 steriliz\$3 disinfect\$3) with (swab pad foam sponge)) and @ad<="20051117"	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S104	0	(luer near3 (clean\$3 steriliz\$3 disinfect\$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S105	49	(luer near3 (clean\$3 steriliz\$3 disinfect\$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S106	12	((("4232677") or ("4610469") or ("4624664") or ("4440207") or ("4432764") or ("4778447") or ("5242425") or ("5694978") or ("6911025") or ("20060030827") or ("5554135") or ("20040004019")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 20:33
S107	18	("20040004019" "20050124970" "4440207" "4626664" "4778447" "5242425" "5547662" "5706944" "6911025" "6994315").PN. ("4444310" "5554135").PN. ("20080177250" "20090062766" "20090149819" "20100047123" "20100049170" "20120039765").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 20:45
S109	1148	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S110	156	(604/534).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S111	312	(604/535).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S112	45	(604/536).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S113	337	(604/537).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S114	190	(15/104.03).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:40
S115	797	(15/104.04).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S116	398	(15/104.062).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S117	493	(15/104.92).CCLS.	US-PGPUB; USPAT;	OR	OFF	2013/08/08 14:43

			USOCR			
S118	941	(15/104.93).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S119	917	(15/104.94).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S120	2913	(422/28).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:46
S121	2	((("4440207") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 15:15
S122	128	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$ or US-20040004019-\$).did. or (US-20060039742-\$ or US-20080021392-\$ or US-20080021381-\$ or US-20080107564-\$ or US-20090024096-\$ or US-20090041619-\$ or US-20090297400-\$ or US-20100049170-\$ or US-20100047123-\$ or US-20100064456-\$ or US-20100100056-\$ or US-20100242993-\$ or US-20100286637-\$ or US-20100292673-\$ or US-20100296968-\$ or US-20110054440-\$ or US-20110150958-\$ or US-20110184382-\$ or US-20110236258-\$ or US-20110314619-\$ or US-20120039765-\$ or US-20010016589-\$ or US-20030162839-\$ or US-20080075761-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/08 20:13

		7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$.did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$ or US-7704935-\$ or US-7866907-\$ or US-8113731-\$ or US-6488942-\$ or US-6846846-\$ or US-8167847-\$ or US-8206514-\$ or US-8252247-\$ or US-8388894-\$ or US-4610469-\$ or US-3595419-\$ or US-4800904-\$ or US-7857793-\$.did. or (US-2961682-\$ or US-0877946-\$.did. or (US-20080086091-\$).did.				
S124	0	S122 and (partial half) near2 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S125	0	S122 and (partial half quarter length) near2 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S126	6	S122 and (partial half quarter length) with thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S127	2605	(cap connector) with (partial half quarter length) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S128	918	(cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S129	68	valve same (cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S130	6	medical and valve same (cap connector) with (partial half quarter) near3 thread\$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S131	9	valve same (cap connector) with (partial half quarter) near3 thread\$3 with inner	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:22
S132	5	("20040004019" "4440207" "4778447" "5242425" "6117114").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:31
S133	7	("20050147524" "4280632" "4671306" "4991629" "5954957" "6116468" "6227391").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:32
S134	129	(US-20070112333-\$ or US-20020123440-\$ or US-20070202177-\$ or US-20080027399-\$ or US-20080177250-\$ or US-20090149819-\$ or US-20050222542-\$ or US-20070176117-\$ or US-20050124970-\$ or US-20080038167-\$ or US-20080132880-\$ or US-20080235888-\$ or US-20060048313-\$ or US-20070225660-\$ or US-20070093762-\$ or	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2014/01/13 10:34

		US-20080086091-\$ or US-20090008393-\$ or US-20080095680-\$ or US-20090028750-\$ or US-20090062766-\$ or US-20080147047-\$ or US-20060030827-\$ or US-20030153865-\$ or US-20040258560-\$ or US-20050147524-\$ or US-20040004019-\$).did. or (US-20060039742-\$ or US-20080021392-\$ or US-20080021381-\$ or US-20080107564-\$ or US-20090024096-\$ or US-20090041619-\$ or US-20090297400-\$ or US-20100049170-\$ or US-20100047123-\$ or US-20100064456-\$ or US-20100100056-\$ or US-20100242993-\$ or US-20100286637-\$ or US-20100292673-\$ or US-20100296968-\$ or US-20110054440-\$ or US-20110150958-\$ or US-20110184382-\$ or US-20110236258-\$ or US-20110314619-\$ or US-20120039765-\$ or US-20010016589-\$ or US-20030162839-\$ or US-20080075761-\$).did. or (US-5334388-\$ or US-5439681-\$ or US-5512199-\$ or US-5547662-\$ or US-5706944-\$ or US-5817344-\$ or US-6723689-\$ or US-4655762-\$ or US-5607683-\$ or US-6651956-\$ or US-4232677-\$ or US-6089541-\$ or US-4354490-\$ or US-4402691-\$ or US-4432764-\$ or US-4440207-\$ or US-4778447-\$ or US-5554135-\$ or US-5792120-\$ or US-6045539-\$ or US-6171287-\$ or US-4243035-\$ or US-5433705-\$ or US-0877946-\$ or US-7198611-\$ or US-4417890-\$).did. or (US-7682561-\$ or US-6994315-\$ or US-4624664-\$ or US-4431424-\$ or US-4439188-\$ or US-5195957-\$ or US-2636644-\$ or US-4022206-\$ or US-4432766-\$ or US-4738668-\$ or US-6911025-\$ or US-7083605-\$ or US-7452349-\$ or US-7232419-\$ or US-D596308-\$ or US-4301567-\$ or US-6813797-\$ or US-7704002-\$ or US-6207201-\$ or US-4282891-\$ or US-4671306-\$ or US-5274874-\$ or US-5639310-\$ or US-5694978-\$ or US-6708363-\$ or US-5242425-\$ or US-5989229-\$).did. or (US-7763006-\$ or US-7780794-\$ or US-7794675-\$ or US-7799010-\$ or US-7922701-\$ or US-7972322-\$ or US-7985302-\$ or US-8065773-\$ or US-8069523-\$ or US-7704935-\$ or US-7866907-\$ or US-8113731-\$ or US-6488942-\$ or US-6846846-\$ or US-8167847-\$ or US-8206514-\$ or US-8252247-\$ or US-8388894-\$ or US-4610469-\$ or US-3595419-\$ or US-4800904-\$ or US-7857793-\$ or US-6117114-\$).did. or (US-2961682-\$ or US-0877946-\$).did. or (US-20080086091-\$).did.				
S135	22	(US-20070225660-\$ or US-20060030827-\$ or US-20050124970-\$ or US-20040258560-\$ or US-20030153865-	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:34

EAST Search History

	\$.did. or (US-7682561-\$ or US-7452349-\$ or US-7198611-\$ or US-7083605-\$ or US-6994315-\$ or US-6911025-\$ or US-6708363-\$ or US-5694978-\$ or US-5242425-\$ or US-5195957-\$ or US-4778447-\$ or US-4671306-\$ or US-4624664-\$ or US-4432764-\$ or US-4282891-\$ or US-2961682-\$).did. or (US-2961682-\$).did.				

EAST Search History (Interference)

< This search history is empty >

1/ 13/ 2014 1:17:49 PM

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 04/07/2014 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirtan & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 04/07/2014	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant and examiner discussed the Reasons for Allowance mailed on 1/21/2014.

The applicant and examiner discussed the statement of the reasons for allowance as it would specifically apply to allowed independent claim 79.

The applicant noted that the claim language in claim 79 states, *inter alia*, "... the housing including a thread on an inner wall of the cavity for engaged external threads on the access portion of the patient fluid line access valve; ... the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion..."

The applicant noted that the examiner's statement of reasons for allowance included the statement that "... and rotational movement of the threads relative to another causes the end face to advance into the cavity resulting in the end face contact[ing] the wet pad such that both the end face and at least a portion of the external threads of the access valve are disinfected in combination with the other elements of the claims."

The applicant noted that this specific recitation is not specifically required by the claim language of claim 79. In other words, there is no required "rotational movement" claimed in claim 79 to cause disinfecting of the end face and at least a portion of the external threads and it is thus not required for allowability of claim 79.

In response, the examiner first references 37 CFR 1.104(e) and MPEP 1302.14. A reasons for allowance is at the discretion of the examiner to make the record as clear and complete as reasonably possible. It is the personal opinion of the examiner and should not create an estoppel. Further, failure of the applicant to comment on the examiner's statement of reasons for allowance should not be treated as acquiescence to the examiner's statement. The record of prosecution as a whole defines the reasons for allowance.

To make the record clear, the examiner notes that claim 79 recites "... the housing including a thread ... for engaging the external threads on the access portion ..." During engagement one of ordinary skill in the art would readily recognize that "rotational movement" of the threads relative to another will normally occur during engagement of the housing and the patient fluid line access valve. That is the nature of threads.

However, the applicant's point is that such "rotational movement" is not required by claim 79 to perform the act of disinfecting the end face and at least a portion of the external threads.

The examiner agrees. The specific claim language of claim 79 reads "... the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion ..."

When the housing is positioned over and covers the access portion the wet pad is positioned to disinfect the end face and at least a portion of the external threads. No rotational movement at this point is necessary to disinfect. In other words, the housing has fully engaged the access portion so that the housing is positioned over and covers the access portion. As the prosecution history makes clear, the prior art does not teach or suggest this claim recitation in combination with the other elements of the claims.

For example, Genatempo et al (USPN 4440207) does not teach or suggest this limitation because when the housing (10) is positioned over and covers the access portion (40) the device would be configured as shown in Fig 3 which shows that the end face (distal end of 40 located near reference arrow 42) cannot be contacted by the wet pad (24) to be disinfected because the end face is located in cavity (30) below the wet pad (24).

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

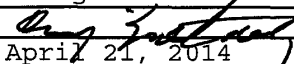
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

71562 7590 01/21/2014
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Craig Metcalf	(Depositor's name)
	(Signature)
April 21, 2014	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168

TITLE OF INVENTION: Patient fluid line access valve antimicrobial cap/cleaner

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	04/21/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
GILBERT, ANDREW M	3763	604-533000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Jeanne Lukasavage
2 Craig Metcalf
3 Kirton McConkie

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Becton, Dickinson and Company Franklin Lakes, New Jersey

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☒ Advance Order - # of Copies 2

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 500843 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

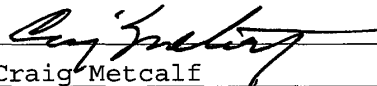
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature 
Typed or printed name Craig Metcalf

Date 4/21/14
Registration No. 31,398

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		Lloyd Craig Metcalf/Kris Haley		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Printed Copy of Patent - No Color	8001	2	3	6
Total in USD (\$)				966

Electronic Acknowledgement Receipt	
EFS ID:	18811269
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	21-APR-2014
Filing Date:	17-NOV-2005
Time Stamp:	11:53:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$966
RAM confirmation Number	7119
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	P_6836_IssueFeeTrans_042114.pdf	91368 afc048d1e8df0c56db1981f708ea86b72cd72ef7	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31600 bc42e834af59de10bb6975de41d4ebcf3bf03aa0	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			122968		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

The application has been amended as follows:

In claim 84, In 3-4 the phrase "the patient fluid line access valve" has been changed to --the threaded patient fluid line access valve--.

Change(s) applied In claim 84, In ⁶~~3~~ the phrase "the patient fluid line access valve" has been
to document,
/J.C.J./ changed to --the threaded patient fluid line access valve--.
2/16/2014

ALLOWANCE

8. Claims 69-70, 72-88 are allowed.

9. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The prior art does not disclose or render obvious the combination as claimed specifically including housing having a wet pad positioned within a cavity having an internal thread, where the wet pad contacts the end face of an externally threaded patient fluid line access valve when the housing is positioned over and covers the access valve and rotational movement of the threads relative to another causes the end face to advance into the cavity resulting in the end face contacts the wet pad such that both the end face and at least a portion of the external threads of the access valve are disinfected in combination with the other elements of the claims.

10. The closest prior art is Genatempo (4440207), which as discussed in the Non-Final office action teaches disinfecting at least a portion of the external threads,



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	06/03/2014	8740864	P-6836	9168

71562 7590 05/14/2014
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirtan & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 1701 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Minh Quang Hoang, Sandy, UT;
Jonathan Karl Burkholz, Salt Lake City, UT;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of New Jersey on the following: ____ Trademarks or ☒ Patents. (____ the patent action involves 35 U.S.C. § 292.)		
DOCKET NO. 2:14-cv-03512-WJM-MF	DATE FILED 6/3/2014	U.S. DISTRICT COURT NEWARK, NJ
PLAINTIFF CATHETER CONNECTIONS, INC.		DEFENDANT IVERA MEDICAL CORP.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,740,864	JUNE 3, 2014	BECTON, DICKINSON and COMPANY ("BD")
2		
3		
4		
5		

In the above--entitled case, the following patent(s)/ trademark(s) have been included:		
DATE INCLUDED	INCLUDED BY ____ Amendment ____ Answer ____ Cross Bill ____ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above--entitled case, the following decision has been rendered or judgement issued:	
DECISION/JUDGEMENT	

CLERK William T. Walsh	(BY) DEPUTY CLERK s/ Dianne C. Richards	DATE 6/3/2014

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

To:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Southern District of California on the following: X Patents or Trademarks:

DOCKET NO.	DATE FILED	US District Court Southern District of California
3:14-cv-01345-JAH-BLM	6/3/14	San Diego, CA
PLAINTIFF		DEFENDANT
Ivera Medical Corporation, et al.		Hospira, Inc.
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.
1. 8,740,864	6.	11.
2.	7.	12.
3.	8.	13.
4.	9.	14.
5.	10.	15.

In the above-entitled case, the following patents(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY	
	<u> </u> Amendment <u> </u> Answer <u> </u> Cross Bill <u> </u> Other Pleading	
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.
1.	6.	11.
2.	7.	12.
3.	8.	13.
4.	9.	14.
5.	10.	15.

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT		
CLERK	(BY) DEPUTY CLERK	DATE
John Morrill, Clerk of Court		

To:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Southern District of California on the following: X Patents or Trademarks:

DOCKET NO.	DATE FILED	US District Court Southern District of California
3:14-cv-01348-GPC-JLB	6/3/14	San Diego, CA
PLAINTIFF		DEFENDANT
Ivera Medical Corporation, et al.		Excelsior Medical Corporation, et al.
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.
1. 8,740,864	6.	11.
2.	7.	12.
3.	8.	13.
4.	9.	14.
5.	10.	15.

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	Amendment <u> </u> Answer <u> </u> Cross Bill <u> </u> Other Pleading <u> </u>		
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	
1.	6.	11.	
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4.	9.	14.	
5.	10.	15.	

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT

CLERK	(BY) DEPUTY CLERK	DATE
John Morrill, Clerk of Court		

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of New Jersey on the following: ____ Trademarks or X Patents. (____ the patent action involves 35 U.S.C. § 292.)		
DOCKET NO. 1:14-cv-03502-NLH-AMD	DATE FILED 6/5/2014	U.S. DISTRICT COURT CAMDEN, NJ
PLAINTIFF EXCELSIOR MEDICAL CORP.		DEFENDANT IVERA MEDICAL CORP.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,740,864	6/03/2014	BECTON, DICKINSON AND COMPANY
2		
3		
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:		
DATE INCLUDED	INCLUDED BY	
	____ Amendment ____ Answer ____ Cross Bill ____ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:	
DECISION/JUDGEMENT	

CLERK William T. Walsh	(BY) DEPUTY CLERK s/ Brian D. Kemner	DATE 6/5/2014

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/281,711	Confirmation No.: 9168
Filed	:	November 17, 2005	
Patent No.	:	8,740,864 B2	
Issue Date	:	June 3, 2014	
Applicants	:	Minh Quang Hoang et al.	
Title	:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	
TC/A.U.	:	3767	
Examiner	:	Andrew M. Gilbert	
Docket No.	:	P-6836	
Customer No.	:	71562	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION
OF THE PATENT TERM ADJUSTMENT

Dear Sir:

This paper is being submitted in response to the Issue Notification mailed May 14, 2014. In the Issue Notification, the Office provides a patent term adjustment of 1701 days. Pursuant to 37 C.F.R. 1.705, Applicant requests reconsideration of this patent term adjustment because the correct adjustment is 1834 days for the reasons provided below in the Statement of Facts.

Appl. No.: 11/281,711
Patent No.: 8,740,864 B2
Issue Date: June 3, 2014
Request for Reconsideration of PTA

STATEMENT OF FACTS

Applicant agrees with the Office's calculation of the patent term adjustment ("PTA") except with regard to the number of B delay days. The calculation of 724 days of B delay correctly identifies the number of days that accrued prior to the filing of an RCE. However, under the Federal Circuit's recent decisions in *Novartis*¹ and *Exelixis*², the B delay should also include each day from the mailing of the notice of allowance until the patent issues. The notice of allowance was mailed on 1/21/2014 and the patent issued on 6/3/2014. Therefore, an additional 133 days should be added to the B delay for this post allowance period. The total B delay is therefore 857 days.

Accounting for these additional 133 days yields a total of 1834 days of patent term adjustment. No terminal disclaimer has been filed in this application. Also, the current calculation already accounts for the 171 days of applicant delay that can be considered as a failure to engage in reasonable efforts to conclude processing or examination of the application. Applicant therefore respectfully requests that current patent term adjustment be modified to reflect the correct number of 1834 days.

Respectfully submitted,


Craig Metcalf
Reg. No. 31,398
Attorney for Applicant

Date: July 7, 2014

KIRTON | McCONKIE
50 East South Temple
Salt Lake City, Utah 84111
Telephone: 801-328-3600

¹ *Novartis AG v. Lee*, 740 F.3d 593, 109 U.S.P.Q.2d 1385 (Fed. Cir. 2014).

² *Exelixis, Inc. v. Lee*, 550 Fed.Appx. 894 (Fed. Cir. 2014).

Electronic Patent Application Fee Transmittal				
Application Number:		11281711		
Filing Date:		17-Nov-2005		
Title of Invention:		Patient fluid line access valve antimicrobial cap/cleaner		
First Named Inventor/Applicant Name:		Minh Quang Hoang		
Filer:		Lloyd Craig Metcalf/Kris Haley		
Attorney Docket Number:		P-6836		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Application for patent term adjustment	1455	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				200

Electronic Acknowledgement Receipt	
EFS ID:	19508439
Application Number:	11281711
International Application Number:	
Confirmation Number:	9168
Title of Invention:	Patient fluid line access valve antimicrobial cap/cleaner
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836
Receipt Date:	07-JUL-2014
Filing Date:	17-NOV-2005
Time Stamp:	17:04:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$200
RAM confirmation Number	4159
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Patent Term Adjustment Petition	P_6836_ReqReconsiderPTA_070714.pdf	65908 8c8c95133e99d405381ad33034b3297e11c92731	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	29868 93b68ebce42b9fc5a981ee8cfd76932d11c0b97	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			95776		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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DOCKET NO. 1:14-cv-03502-NLH-AMD	DATE FILED 6/5/2014	U.S. DISTRICT COURT CAMDEN, NJ
PLAINTIFF EXCELSIOR MEDICAL CORP.		DEFENDANT IVERA MEDICAL CORP.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,740,864	6/03/2014	BECTON, DICKINSON AND COMPANY
2		
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:		
DATE INCLUDED	INCLUDED BY ____ Amendment ____ Answer ____ Cross Bill ____ Other Pleading	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

Case IPR2014-00880
Patent 8,740,864 B2

Before PHILLIP J. KAUFFMAN, HYUN J. JUNG, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Excelsior Medical Corporation, filed a Corrected Petition, requesting an *inter partes* review of claims 10–14 of US Patent No. 8,740,864 B2 (Ex. 2001, “the ’864 patent”). Paper 6 (“Pet.”). Subsequently, Patent Owner, Becton, Dickinson and Company, filed a Preliminary Response. Paper 11 (“Prelim. Resp.”).

After considering the record to this point in the proceeding, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to a challenge to the patentability of claims 10, 12, and 14 of the ’864 patent, but has not made such a showing with regard to claims 11 and 13. *See* 35 U.S.C. § 314.

II. BACKGROUND

A. *Related Proceedings*

Petitioner indicates that the ’864 patent is involved in the following lawsuits: *Excelsior Medical Corp. v. Becton, Dickinson and Co.* 14-cv-03502 (D.N.J.), and *Ivera Medical Corp. v. Excelsior Medical Corp.*, 14-cv-1348 (S.D. Cal.). Pet. 1–2.

Patent Owner indicates the following matters may be affected by this proceeding: *Catheter Connections, Inc., v. Ivera Medical Corp.*, 2:2014-cv-03512 (D.N.J.); *Hospira, Inc. v. Ivera Medical Corp.*, 2:2014-cv-03513 (D.N.J.); *Ivera Medical Corp. v. Catheter Connections, Inc.*, 3:14-cv-01346 (S.D. Cal.); *Ivera Medical Corp. v. Hospira, Inc.*, 3:14-cv-01345 (S.D. Cal.). Paper 8, 2.

B. Asserted Grounds of Unpatentability and Prior Art

Petitioner presents the following grounds of unpatentability under 35 U.S.C. § 103:

References	Claims challenged
White ¹ , Harding ² , and Genatempo ³	10
White, Harding, Genatempo, and Paradis ⁴	11
White, Harding, and Genatempo	12
White, Harding, Genatempo, and Busch ⁵	13
White, Harding, Genatempo, and Busch	14
Menyhay ⁶ and Genatempo	10
Menyhay, Genatempo, and Paradis	11
Menyhay and Genatempo	12
Menyhay, Genatempo, and Busch	13
Menyhay and Genatempo	14

Pet. 4–5

¹ Ex. 1021, US Patent No. 5,242,425 (Sept. 7, 1993).

² Ex. 1022, US Patent Pub. US 2003/0109853 A1 (June 12, 2003).

³ Ex. 1024, US Patent No. 4,440,207 (Apr. 3, 1984).

⁴ Ex. 1025, US Patent No. 6,117,114 (Sept. 12, 2000).

⁵ Ex. 1026, US Patent Pub. US 2004/0004019 A1 (Jan. 8, 2004).

⁶ Ex. 1029, US Patent No. 5,554,135 (Sept. 10, 1996).

Figure 2 is a cross-sectional view of the first embodiment of cap/cleaner device 10. *Id.* at 1:46–47.

Cap/cleaner 10 includes housing 12 having cap end 14 and cleaning end 16. *Id.* at 2:1–3. Cleaning end 16 is covered by lid 20 which may be removed to expose wet pad 22. *Id.* at 2:19–20, 24–28; Fig. 2. Cap end 14 is open and contains thread 18 for interlocking to thread A4 of access portion A10 of access valve A. *Id.* at 2:10–12, 18–19, 60–63; Fig. 3. In an alternative embodiment, the pad in the cap end (pad 80) may be either a dry pad or a wet pad. *Id.* at 4:63–65; Fig. 7.

Patient fluid line access valve A includes access portion A10 formed by the exposed surface of septum A6 and at least a portion of the exposed surface of housing A2. *Id.* at 2:4–7. Patient fluid line access valve A also includes thread A4.⁷ *Id.* at 2:3–4.

The '864 patent includes claims 1–19, of which, claims 10–14 are challenged in this proceeding. Independent claim 10, the sole independent claim challenged, is illustrative and reads as follows:

10. A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve;

⁷ Thread A4 corresponds to the “external threads” recited in claim 10.

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad.

Ex. 2001, 6:3–26.

III. CLAIM CONSTRUCTION

Our analysis necessitates construction of the following terms under the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b).

A. external threads on the access portion proximate the septum

Independent claim 10 is directed to a device for maintaining a patient fluid line access valve. The preamble recites that the device has an access portion with an end face that includes a septum and “external threads on the access portion proximate the septum.”⁸

⁸ We note that this limitation was not in the originally filed claims. *See* Ex. 1009, Amendment B 2. Neither party identifies, nor do we discern, anything in the prosecution history that would aid our interpretation of this limitation.

Neither party provides an explicit construction of this limitation. *See* Pet. 18–19; Prelim. Resp. 23–25. However, Petitioner’s argument that Harding’s external threads correspond to external threads as claimed because those threads are “near the septum,” implies that “proximate” as claimed means “near.” *See* Pet. 23.

The preamble’s recitation of external threads on the access portion is necessary to understand the requirement in the claim body that the open end of the housing for covering the access portion of the patient fluid line access valve includes a thread for engaging the external threads on the access portion of the patient fluid line access valve. For this same reason, the preamble serves as an antecedent basis for the external threads recited in the body of the claim.

The Specification does not expressly define “proximate,” and the term is not used in the ’864 patent outside of the claims.⁹ An ordinary meaning of “proximate” is “very near.”¹⁰

The term “near” is a relational term that must be interpreted in context. Here, claim 10 requires that the septum is included in the end face of the access portion and the external threads are on the access portion, proximate the septum. Therefore, claim 10 requires that the external threads are very near the end face of the access portion as

⁹ Independent claim 1 uses the term “proximate” similarly to independent claim 10.

¹⁰ *Proximate Definition*, MERRIAM-WEBSTER ONLINE DICTIONARY, www.merriam-webster.com/dictionary/proximate (visited Oct. 28, 2014).

compared to other positions on the access portion. With this context in mind, we turn to the Specification.

The Specification describes that patient fluid line access valve cap/cleaner device 10 includes access valve A, which includes housing A2, septum A6, and thread A4. Ex. 2001, 2:1–4; Fig. 1. The exposed surface of septum A6 and at least a portion of the exposed surface of housing A2 form access portion A10. *Id.* at 2:4–7; Fig. 1. Consistent with the ordinary meaning of “proximate,” thread A4¹¹ is nearer the end of access portion 10 having septum A6 than to the opposite end of access portion A10. *Id.* The ’864 patent makes no disclosure inconsistent with the ordinary meaning of the term proximate.

On review of the entire patent, the preamble of claim 10 is limiting in that it requires the access portion to include external threads proximate the septum. *See Catalina Marketing Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Therefore, we construe claim 10 to require the external threads to be located on the access portion very near the end face as compared to other parts of the access portion.

B. length

Claim 11 depends from independent claim 10 and recites that the thread of the housing has “a length that is less than the inner circumference” of the inner cavity of the housing. Claim 11 does not refer to the length of the thread along the axial length of the inner

¹¹ Corresponding to “external threads” in claim 10.

cavity of the housing; rather, claim 11 simply refers to the length of the thread.

The Specification does not expressly define “length.” An ordinary meaning of length is “the measurement or extent of something from end to end.” Ex. 2002, CONCISE OXFORD ENGLISH DICTIONARY, 815 (11th ed. 1990); *see also* Prelim. Resp. 24 (citing this definition and a similar definition in Ex. 2003, LONGMAN DICTIONARY OF AMERICAN ENGLISH, 520 (3d ed. 2004)).

The Specification describes that cap device 78 includes inner circumference 82 that defines a cavity, and includes thread or threading 18 “having a length that is less than inner circumference 82.” Ex. 2001, 5:3–6; Fig. 10B. Such description is consistent with the ordinary meaning of length.

Taken in the context of claim 11, the length of the thread refers to the measurement from end to end of that thread. This interpretation is consistent with Petitioner’s assertion that length as claimed refers to the helical length of the thread along the wall of the inner cavity. *See* Pet. 19. Our interpretation differs from Petitioner’s alternative interpretation that length means the axial length. *Id.*

IV. 35 U.S.C. § 325(d)

Under 35 U.S.C. § 325(d), the Board may take into account and reject a petition because the same or substantially the same prior art or argument was presented previously to the Office. Patent Owner asks that the Board exercise its discretion under 35 U.S.C. § 325(d) to reject the Petition because the grounds set forth in the Petition either

rely on the same art (or in one case, a cumulative secondary reference) or the same arguments considered by the Office during the prosecution of the application that issued as the '864 patent. Prelim. Resp. 1, 9. For the reasons given below, we are not persuaded by Patent Owner's arguments under 35 U.S.C. § 325(d). We analyze Patent Owner's contention by addressing the grounds of unpatentability asserted in the Petition in two groups: (1) grounds based at least in part on White, Harding, and Genatempo, and (2) grounds based at least in part on Menyhay and Genatempo. *See* Pet. 4–5.

A. White, Harding, and Genatempo

In each of the grounds of unpatentability that rely at least in part on White, Harding, and Genatempo, Petitioner contends that the external threads of White's access valve are not located as claimed, and proposes to modify White's threads to be positioned as disclosed by Harding. Pet. 4, 21–32; Ex. 1037 ¶ 23. In contrast, during prosecution, the Examiner relied upon White as disclosing external threads as claimed. Ex. 1017, 14; *see also* Prelim. Resp. 9–10 (citing the Fifth Office Action, now Ex. 1017). Therefore, with respect to this limitation, the arguments and prior art previously presented to the Office differ from the grounds of unpatentability in the Petition.

Patent Owner contends this distinction is not meaningful because Petitioner has not established sufficiently that White does not disclose external threads as claimed and because Harding is cumulative to White. Prelim. Resp. 2–9. Petitioner need not

establish that the Examiner was in error. The focus of our inquiry is whether the same or substantially the same prior art or arguments presented in the Petition were previously presented to the Office. As explained above, we determine that they were not.

Regarding Patent Owner's contention that Harding is cumulative to White, we disagree. During prosecution, the Examiner considered the claim term "proximate" to mean "very near," but did not consider the context of claim 10. Ex. 1017, 14. Specifically, without the frame of reference provided by the location of the septum on the end face, the term "very near" has no meaning and effectively reads the term "proximate" out of claim 10. *See also Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (rejecting claim constructions that render phrases in claims superfluous). White's threads (externally threaded shoulder 74) are positioned as far from the septum end (septum 84) of the access portion as is possible while still remaining on the access portion (proximal member 82). Ex. 1021, 7:23-35; Fig. 7.¹²

Consequently, we are not persuaded by Patent Owner's arguments under 35 U.S.C. § 325(d) regarding the combination of White, Harding, and Genatempo.

¹² We are mindful that neither party has construed expressly the limitation at issue, and that our claim construction, which is not based upon a fully developed record, may evolve as this proceeding progresses.

B. Menyhay and Genatempo

In each of the grounds of unpatentability that rely at least in part on Menyhay and Genatempo, Petitioner contends that Menyhay differs from the claimed subject matter in three respects but that Genatempo teaches the limitations not described by Menyhay. Pet. 33–36.

Patent Owner contends that during prosecution, some of the claims were subject to a rejection based upon anticipation by Menyhay, and also contends that Genatempo was considered during prosecution for the same teachings relied upon in the Petition. *See* Prelim. Resp. 4–5, 14–16 (citing the first Office Action, Ex. 1006 and the fourth Office Action, Ex. 1013).

The consideration of Menyhay during prosecution identified by Patent Owner was for anticipation and involved a different claim than what is now claim 10. The consideration of Genatempo during prosecution identified by Patent Owner was in combination with White, not with Menyhay. Patent Owner has not identified, nor do we discern, how the Office considered the combination of Menyhay and Genatempo presented in this Petition during prosecution. *See* Prelim. Resp. 1–20. Nor do the Examiner’s comments in the Notice of Allowance demonstrate that the Examiner expressly considered the subject matter of claim 10 (then claim 79) to be nonobvious over the combination of Menyhay and Genatempo. *See* Ex. 1019, 8–9.

Consequently, we are not persuaded by Patent Owner’s arguments under 35 U.S.C. § 325(d) regarding the combination of Menyhay and Genatempo.

V. ANALYSIS

A. *Independent Claim 10*

Petitioner contends that claim 10 would have been obvious over White, Harding, and Genatempo. Pet. 21–26, 29–30. Alternatively, Petitioner contends that claim 10 would have been obvious over Menyhay and Genatempo. Pet. 32–36, 38–40. Other than the argument based upon 35 U.S.C. § 325(d), Patent Owner presents no arguments against these grounds of unpatentability for claim 10. Prelim. Resp. 20–22.

Petitioner explains how the challenged claim is unpatentable, including specifically alleging where each element is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge. *See* Pet. 21–26, 29–30, 32–36, 38–40. Petitioner provides a rationale for modifying White’s external threads to be positioned as taught by Harding so that at least a portion the external threads is disinfected, and also provides a rationale for adding a removable lid as taught by Genatempo. *Id.* at 22–26. Petitioner provides a supporting declaration that is cited and explained as applicable. *See, e.g.*, Pet. 22 (citing Ex. 1037 ¶ 22). We determine that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claim 10 is unpatentable over White, Harding, and Genatempo and, alternatively, over Menyhay and Genatempo.

B. Dependent Claims 11–14

Patent Owner contends that Petitioner’s grounds of unpatentability against dependent claims 11–14 are deficient because they do not address the limitations of claim 10 from which they depend. Prelim. Resp. 20–21. Petitioner asserts that claim 10 is unpatentable over White, Harding, and Genatempo (Pet. 4, 21–26), followed by a ground of unpatentability based upon White, Harding, Genatempo, and Paradis (Pet. 4, 26–27, 30–31) that explains how the additional limitation of claim 11 would have been obvious in view of Paradis. For this reason, Patent Owner’s argument that the grounds are deficient is unpersuasive.

C. Claim 11

Claim 11 depends from claim 10 and recites, “wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.”

White, Harding, Genatempo, and Paradis

Petitioner contends that claim 11 is unpatentable over White, Harding, Genatempo, and Paradis.¹³ Pet. 4, 26–27, 30–31. Petitioner only identifies a specific portion of Paradis as disclosing threads as claimed. *Id.*

Petitioner’s contention that the length of the internal thread of White would have been a matter of design choice would render

¹³ Viewed as a whole, this ground of unpatentability is over White, Harding, Genatempo, and Paradis, so that the omission of Harding and Genatempo from the heading (Pet. 26) is an unimportant distinction. *See* Pet. 4, 21–27, 29–31.

Paradis superfluous. *See* Pet. 26. The same is true with regard to the contention that it would have been obvious to modify the cap in White to adapt to the external threads of Harding, and the contention that it would be obvious to modify the threads to have the claimed length because it would expose more of the threads to the pad within the cavity to antiseptic. Pet. 26-27 (citing, but not explaining what is contained in Ex. 1037 ¶ 29). This ground of unpatentability is based upon White, Harding, Genatempo, and Paradis, and we will not consider grounds that have not been properly presented. *See* Pet. 4, 26-27, 31 (providing a specific citation to only Paradis with regard to the limitation at issue¹⁴).

Petitioner asserts that Paradis discloses a thread having a length less than the circumference of its cylindrical connector. Pet. 26. Petitioner does not explain cogently how or why a person of ordinary skill in the art would have modified the proposed combination of White, Harding, and Genatempo, to include threads as disclosed by Paradis. Petitioner has the burden to explain how the challenged claim is unpatentable and has not done so sufficiently here. *See* 37 C.F.R. § 42.104(b)(4); *see also Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (obviousness requires more than a showing that the prior art includes separate references covering each limitation of the claims, it must also be shown that a person of ordinary skill in the art would have selected and combined those elements to yield the claimed invention).

¹⁴ *See* 37 C.F.R. § 42.104(b)(5).

Menyhay, Genatempo, and Paradis

Petitioner contends that claim 11 is unpatentable over Menyhay, Genatempo, and Paradis.¹⁵ Pet. 5, 36, 40. Petitioner relies upon Paradis here in a manner that parallels the ground of unpatentability over White, Harding, Genatempo, and Paradis analyzed above. Our analysis there is equally applicable here.

Conclusion

We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 11 is unpatentable over White, Harding, Genatempo, and Paradis or over Menyhay, Genatempo, and Paradis.

D. Claim 12

Claim 12 depends from claim 10 and recites, “wherein the cleaning solution comprises an antimicrobial agent.” Patent Owner presents no arguments against these grounds of unpatentability other than the arguments that we address in sections IV and V.B. above. See Prelim. Resp. 20–22.

White, Harding, and Genatempo, or Menyhay and Genatempo

Petitioner explains how the challenged claim is unpatentable, including specifically alleging where this element is found in White and Menyhay, with citations by exhibit number to the specific portion

¹⁵ Viewed as a whole, this ground of unpatentability is over Menyhay, Genatempo, and Paradis, so that the omission of Genatempo from the heading (Pet. 36) is an unimportant distinction. See Pet. 5, 32–36, 38–40. The same is true with regard to the remaining grounds of unpatentability.

of the evidence that supports the challenge. *See* Pet. 4–5, 27, 31, 36–37, and 40.

Conclusion

We determine that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claim 12 is unpatentable over White, Harding, and Genatempo, and alternatively, over Menyhay and Genatempo.

E. Claim 13

Claim 13 depends from claim 12 and recites, “wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.” Consequently, claim 13 requires the wet pad to be impregnated with either chlorhexidine gluconate or chlorhexidine diacetate.

White, Harding, Genatempo, and Busch

Petitioner contends that claim 13 is unpatentable over White, Harding, Genatempo, and Busch. Pet. 5, 27–28, 30–31. Petitioner acknowledges that White does not disclose an antimicrobial agent as claimed. Pet. 27. Petitioner asserts that it would have been obvious to substitute chlorhexidine gluconate as used in Busch’s skin preparation package for White’s povidone-iodine solution. Pet. 27–28.

White discloses a catheter assembly that includes an outer protective cap 64 that contains a sponge 68 saturated with a disinfectant or antiseptic material that protects the septum of the device from the introduction of pathogens. Ex. 1021, 1:54–55; 6:49–55; 6:67–7:1; Fig. 7. In contrast, Busch does not disclose that skin

preparation package 28 may be utilized to protect a device from the introduction of pathogens; rather, as the name implies, Busch's package 28 contains a solution appropriate for preparing skin for an epidural. Ex. 1026 ¶¶ 11, 26. Petitioner's only evidence that chlorhexidine gluconate and povidone-iodine were known substitutes, is the '864 patent. *See* Pet. 28 (citing Ex. 1002 ¶ 23¹⁶). The portion of the '864 patent cited by Petitioner is not in the *Background* portion of the Specification. Nor does the cited disclosure otherwise indicate that the antimicrobial agents were known substitutes prior to the filing of the application that became the '864 patent.

Consequently, Petitioner has not adequately established that chlorhexidine gluconate as used in Busch's skin preparation package was a known substitute for White's povidone-iodine solution.

Menyhay, Genatempo, and Busch

Petitioner contends that claim 13 is unpatentable over Menyhay, Genatempo, and Busch. Pet. 5, 37, 40–41. Petitioner's ground of unpatentability parallels the ground based upon White, Harding, Genatempo, and Busch, and our analysis there is equally applicable here.

Conclusion

We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 13 is unpatentable over White, Harding, Genatempo, and Busch, or over Menyhay, Genatempo, and Busch.

¹⁶ This is the pre-grant publication of the '864 patent. *See also* Ex. 2001, 2:49–54 (making the same disclosure in the '864 patent).

F. Claim 14

Claim 14 depends from claim 12, and recites, “wherein the cleaning solution is an alcohol-based cleaning solution.”

White, Harding, Genatempo, and Busch

Petitioner contends that claim 14 is unpatentable over White, Harding, Genatempo, and Busch. Pet. 4, 28, 32. Specifically, Petitioner contends that a person of ordinary skill in the art would have substituted Busch’s alcohol-based solution for White’s povidone-iodine. Pet. 28. In addition to the cited disclosure of Busch, Petitioner attempts to support the ground by asserting that a person of ordinary skill in the art would know that it was standard nursing practice to wipe the access port septum with an alcohol wipe prior to accessing the septum. *Id.*

As discussed in section V.E. above, Petitioner has not adequately established the link between use of an agent in a skin preparation package such as disclosed in Busch and use in a device such as White’s. This short-coming is not remedied by Petitioner’s assertion regarding the knowledge of a person of ordinary skill in the art because Petitioner presents only attorney argument, unsupported by evidence. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (Attorney arguments and conclusory statements that are unsupported by factual evidence are entitled to little probative value).

Consequently, Petitioner has not adequately established that isopropyl alcohol as used in Busch’s skin preparation package is a known substitute for White’s povidone-iodine solution.

Menyhay and Genatempo

Petitioner contends that claim 14 is unpatentable over Menyhay and Genatempo. Pet. 5, 37, 41. Specifically, Petitioner asserts that Menyhay discloses use of isopropyl alcohol in the wet pad (sponge 12) of an access valve. Pet. 37, 41. Petitioner explains how the challenged claim is unpatentable, including specifically alleging where each element is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge.

Conclusion

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 14 is unpatentable over White, Harding, Genatempo, and Busch, but has demonstrated such with regard to Menyhay and Genatempo.

VI. CONCLUSION

For the foregoing reasons, we are persuaded that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claims 10, 12, and 14 of the '864 patent, but not with respect to claims 11 and 13.

The Board has not made a final determination on the patentability of any challenged claims.

VII. ORDER

For the reasons given, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '864 patent is instituted on the following grounds:

A. Claims 10 and 12 under 35 U.S.C. § 103 by White, Harding, and Genatempo; and

B. Claims 10, 12, and 14 under 35 U.S.C. § 103 by Menyhay and Genatempo;

FURTHER ORDERED that no other grounds of unpatentability alleged in the Petition are authorized for this *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial commencing on the entry date of this decision.

PETITIONER:

Michael Kenaga
Sean Swidler
patentmail@iphorgan.net

PATENT OWNER:

David Cavanaugh
Heather Petruzzi
Wilmer Cutler Pickering Hale and Dorr LLP
david.cavanaugh@wilmerhale.com
heather.petruzzi@wilmerhale.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

Case IPR2014-00880
Patent 8,740,864 B2

Before PHILLIP J. KAUFFMAN, HYUN J. JUNG, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Excelsior Medical Corporation, filed a Corrected Petition, requesting an *inter partes* review of claims 10–14 of US Patent No. 8,740,864 B2 (Ex. 2001, “the ’864 patent”). Paper 6 (“Pet.”). Subsequently, Patent Owner, Becton, Dickinson and Company, filed a Preliminary Response. Paper 11 (“Prelim. Resp.”).

After considering the record to this point in the proceeding, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to a challenge to the patentability of claims 10, 12, and 14 of the ’864 patent, but has not made such a showing with regard to claims 11 and 13. *See* 35 U.S.C. § 314.

II. BACKGROUND

A. *Related Proceedings*

Petitioner indicates that the ’864 patent is involved in the following lawsuits: *Excelsior Medical Corp. v. Becton, Dickinson and Co.* 14-cv-03502 (D.N.J.), and *Ivera Medical Corp. v. Excelsior Medical Corp.*, 14-cv-1348 (S.D. Cal.). Pet. 1–2.

Patent Owner indicates the following matters may be affected by this proceeding: *Catheter Connections, Inc. v. Ivera Medical Corp.*, 2:2014-cv-03512 (D.N.J.); *Hospira, Inc. v. Ivera Medical Corp.*, 2:2014-cv-03513 (D.N.J.); *Ivera Medical Corp. v. Catheter Connections, Inc.*, 3:14-cv-01346 (S.D. Cal.); *Ivera Medical Corp. v. Hospira, Inc.*, 3:14-cv-01345 (S.D. Cal.). Paper 8, 2.

B. Asserted Grounds of Unpatentability and Prior Art

Petitioner presents the following grounds of unpatentability under 35 U.S.C. § 103:

References	Claims challenged
White ¹ , Harding ² , and Genatempo ³	10
White, Harding, Genatempo, and Paradis ⁴	11
White, Harding, and Genatempo	12
White, Harding, Genatempo, and Busch ⁵	13
White, Harding, Genatempo, and Busch	14
Menyhay ⁶ and Genatempo	10
Menyhay, Genatempo, and Paradis	11
Menyhay and Genatempo	12
Menyhay, Genatempo, and Busch	13
Menyhay and Genatempo	14

Pet. 4–5

¹ Ex. 1021, US Patent No. 5,242,425 (Sept. 7, 1993).

² Ex. 1022, US Patent Pub. US 2003/0109853 A1 (June 12, 2003).

³ Ex. 1024, US Patent No. 4,440,207 (Apr. 3, 1984).

⁴ Ex. 1025, US Patent No. 6,117,114 (Sept. 12, 2000).

⁵ Ex. 1026, US Patent Pub. US 2004/0004019 A1 (Jan. 8, 2004).

⁶ Ex. 1029, US Patent No. 5,554,135 (Sept. 10, 1996).

C. The '864 Patent

The '864 patent is titled "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner," and relates to a device for antiseptically maintaining a patient fluid line access valve. Ex. 2001, 1:34–35.

Figure 1 is reproduced below:

FIG. 1

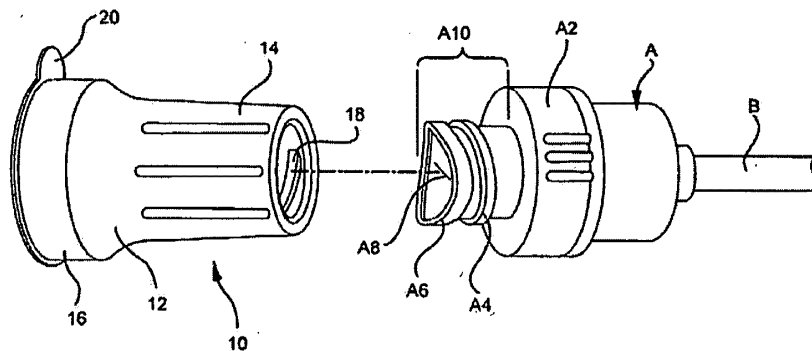


Figure 1 is an exploded view of a first embodiment of the device that includes patient fluid line access valve cap/cleaner device 10 and patient fluid line access valve A. *Id.* at 1:43–45; 1:66–2:1.

Figure 2 is reproduced below:

FIG. 2

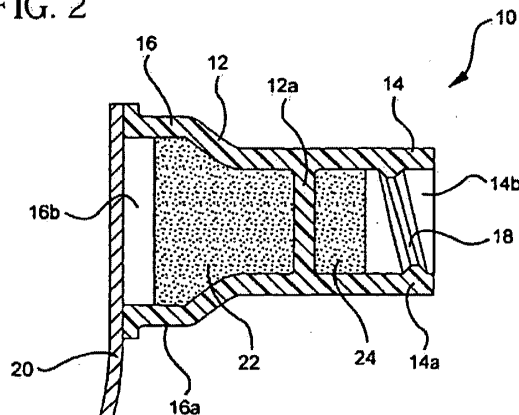


Figure 2 is a cross-sectional view of the first embodiment of cap/cleaner device 10. *Id.* at 1:46–47.

Cap/cleaner 10 includes housing 12 having cap end 14 and cleaning end 16. *Id.* at 2:1–3. Cleaning end 16 is covered by lid 20 which may be removed to expose wet pad 22. *Id.* at 2:19–20, 24–28; Fig. 2. Cap end 14 is open and contains thread 18 for interlocking to thread A4 of access portion A10 of access valve A. *Id.* at 2:10–12, 18–19, 60–63; Fig. 3. In an alternative embodiment, the pad in the cap end (pad 80) may be either a dry pad or a wet pad. *Id.* at 4:63–65; Fig. 7.

Patient fluid line access valve A includes access portion A10 formed by the exposed surface of septum A6 and at least a portion of the exposed surface of housing A2. *Id.* at 2:4–7. Patient fluid line access valve A also includes thread A4.⁷ *Id.* at 2:3–4.

The '864 patent includes claims 1–19, of which, claims 10–14 are challenged in this proceeding. Independent claim 10, the sole independent claim challenged, is illustrative and reads as follows:

10. A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve;

⁷ Thread A4 corresponds to the “external threads” recited in claim 10.

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion; and

a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad.

Ex. 2001, 6:3–26.

III. CLAIM CONSTRUCTION

Our analysis necessitates construction of the following terms under the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b).

A. external threads on the access portion proximate the septum

Independent claim 10 is directed to a device for maintaining a patient fluid line access valve. The preamble recites that the device has an access portion with an end face that includes a septum and “external threads on the access portion proximate the septum.”⁸

⁸ We note that this limitation was not in the originally filed claims. *See* Ex. 1009, Amendment B 2. Neither party identifies, nor do we discern, anything in the prosecution history that would aid our interpretation of this limitation.

Neither party provides an explicit construction of this limitation. *See* Pet. 18–19; Prelim. Resp. 23–25. However, Petitioner’s argument that Harding’s external threads correspond to external threads as claimed because those threads are “near the septum,” implies that “proximate” as claimed means “near.” *See* Pet. 23.

The preamble’s recitation of external threads on the access portion is necessary to understand the requirement in the claim body that the open end of the housing for covering the access portion of the patient fluid line access valve includes a thread for engaging the external threads on the access portion of the patient fluid line access valve. For this same reason, the preamble serves as an antecedent basis for the external threads recited in the body of the claim.

The Specification does not expressly define “proximate,” and the term is not used in the ’864 patent outside of the claims.⁹ An ordinary meaning of “proximate” is “very near.”¹⁰

The term “near” is a relational term that must be interpreted in context. Here, claim 10 requires that the septum is included in the end face of the access portion and the external threads are on the access portion, proximate the septum. Therefore, claim 10 requires that the external threads are very near the end face of the access portion as

⁹ Independent claim 1 uses the term “proximate” similarly to independent claim 10.

¹⁰ *Proximate Definition*, MERRIAM-WEBSTER ONLINE DICTIONARY, www.merriam-webster.com/dictionary/proximate (visited Oct. 28, 2014).

compared to other positions on the access portion. With this context in mind, we turn to the Specification.

The Specification describes that patient fluid line access valve cap/cleaner device 10 includes access valve A, which includes housing A2, septum A6, and thread A4. Ex. 2001, 2:1–4; Fig. 1. The exposed surface of septum A6 and at least a portion of the exposed surface of housing A2 form access portion A10. *Id.* at 2:4–7; Fig. 1. Consistent with the ordinary meaning of “proximate,” thread A4¹¹ is nearer the end of access portion 10 having septum A6 than to the opposite end of access portion A10. *Id.* The ’864 patent makes no disclosure inconsistent with the ordinary meaning of the term proximate.

On review of the entire patent, the preamble of claim 10 is limiting in that it requires the access portion to include external threads proximate the septum. *See Catalina Marketing Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Therefore, we construe claim 10 to require the external threads to be located on the access portion very near the end face as compared to other parts of the access portion.

B. length

Claim 11 depends from independent claim 10 and recites that the thread of the housing has “a length that is less than the inner circumference” of the inner cavity of the housing. Claim 11 does not refer to the length of the thread along the axial length of the inner

¹¹ Corresponding to “external threads” in claim 10.

cavity of the housing; rather, claim 11 simply refers to the length of the thread.

The Specification does not expressly define “length.” An ordinary meaning of length is “the measurement or extent of something from end to end.” Ex. 2002, CONCISE OXFORD ENGLISH DICTIONARY, 815 (11th ed. 1990); *see also* Prelim. Resp. 24 (citing this definition and a similar definition in Ex. 2003, LONGMAN DICTIONARY OF AMERICAN ENGLISH, 520 (3d ed. 2004)).

The Specification describes that cap device 78 includes inner circumference 82 that defines a cavity, and includes thread or threading 18 “having a length that is less than inner circumference 82.” Ex. 2001, 5:3–6; Fig. 10B. Such description is consistent with the ordinary meaning of length.

Taken in the context of claim 11, the length of the thread refers to the measurement from end to end of that thread. This interpretation is consistent with Petitioner’s assertion that length as claimed refers to the helical length of the thread along the wall of the inner cavity. *See* Pet. 19. Our interpretation differs from Petitioner’s alternative interpretation that length means the axial length. *Id.*

IV. 35 U.S.C. § 325(d)

Under 35 U.S.C. § 325(d), the Board may take into account and reject a petition because the same or substantially the same prior art or argument was presented previously to the Office. Patent Owner asks that the Board exercise its discretion under 35 U.S.C. § 325(d) to reject the Petition because the grounds set forth in the Petition either

rely on the same art (or in one case, a cumulative secondary reference) or the same arguments considered by the Office during the prosecution of the application that issued as the '864 patent. Prelim. Resp. 1, 9. For the reasons given below, we are not persuaded by Patent Owner's arguments under 35 U.S.C. § 325(d). We analyze Patent Owner's contention by addressing the grounds of unpatentability asserted in the Petition in two groups: (1) grounds based at least in part on White, Harding, and Genatempo, and (2) grounds based at least in part on Menyhay and Genatempo. *See* Pet. 4–5.

A. White, Harding, and Genatempo

In each of the grounds of unpatentability that rely at least in part on White, Harding, and Genatempo, Petitioner contends that the external threads of White's access valve are not located as claimed, and proposes to modify White's threads to be positioned as disclosed by Harding. Pet. 4, 21–32; Ex. 1037 ¶ 23. In contrast, during prosecution, the Examiner relied upon White as disclosing external threads as claimed. Ex. 1017, 14; *see also* Prelim. Resp. 9–10 (citing the Fifth Office Action, now Ex. 1017). Therefore, with respect to this limitation, the arguments and prior art previously presented to the Office differ from the grounds of unpatentability in the Petition.

Patent Owner contends this distinction is not meaningful because Petitioner has not established sufficiently that White does not disclose external threads as claimed and because Harding is cumulative to White. Prelim. Resp. 2–9. Petitioner need not

establish that the Examiner was in error. The focus of our inquiry is whether the same or substantially the same prior art or arguments presented in the Petition were previously presented to the Office. As explained above, we determine that they were not.

Regarding Patent Owner's contention that Harding is cumulative to White, we disagree. During prosecution, the Examiner considered the claim term "proximate" to mean "very near," but did not consider the context of claim 10. Ex. 1017, 14. Specifically, without the frame of reference provided by the location of the septum on the end face, the term "very near" has no meaning and effectively reads the term "proximate" out of claim 10. *See also Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (rejecting claim constructions that render phrases in claims superfluous). White's threads (externally threaded shoulder 74) are positioned as far from the septum end (septum 84) of the access portion as is possible while still remaining on the access portion (proximal member 82). Ex. 1021, 7:23-35; Fig. 7.¹²

Consequently, we are not persuaded by Patent Owner's arguments under 35 U.S.C. § 325(d) regarding the combination of White, Harding, and Genatempo.

¹² We are mindful that neither party has construed expressly the limitation at issue, and that our claim construction, which is not based upon a fully developed record, may evolve as this proceeding progresses.

B. Menyhay and Genatempo

In each of the grounds of unpatentability that rely at least in part on Menyhay and Genatempo, Petitioner contends that Menyhay differs from the claimed subject matter in three respects but that Genatempo teaches the limitations not described by Menyhay. Pet. 33–36.

Patent Owner contends that during prosecution, some of the claims were subject to a rejection based upon anticipation by Menyhay, and also contends that Genatempo was considered during prosecution for the same teachings relied upon in the Petition. *See* Prelim. Resp. 4–5, 14–16 (citing the first Office Action, Ex. 1006 and the fourth Office Action, Ex. 1013).

The consideration of Menyhay during prosecution identified by Patent Owner was for anticipation and involved a different claim than what is now claim 10. The consideration of Genatempo during prosecution identified by Patent Owner was in combination with White, not with Menyhay. Patent Owner has not identified, nor do we discern, how the Office considered the combination of Menyhay and Genatempo presented in this Petition during prosecution. *See* Prelim. Resp. 1–20. Nor do the Examiner’s comments in the Notice of Allowance demonstrate that the Examiner expressly considered the subject matter of claim 10 (then claim 79) to be nonobvious over the combination of Menyhay and Genatempo. *See* Ex. 1019, 8–9.

Consequently, we are not persuaded by Patent Owner’s arguments under 35 U.S.C. § 325(d) regarding the combination of Menyhay and Genatempo.

V. ANALYSIS

A. *Independent Claim 10*

Petitioner contends that claim 10 would have been obvious over White, Harding, and Genatempo. Pet. 21–26, 29–30. Alternatively, Petitioner contends that claim 10 would have been obvious over Menyhay and Genatempo. Pet. 32–36, 38–40. Other than the argument based upon 35 U.S.C. § 325(d), Patent Owner presents no arguments against these grounds of unpatentability for claim 10. Prelim. Resp. 20–22.

Petitioner explains how the challenged claim is unpatentable, including specifically alleging where each element is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge. *See* Pet. 21–26, 29–30, 32–36, 38–40. Petitioner provides a rationale for modifying White’s external threads to be positioned as taught by Harding so that at least a portion the external threads is disinfected, and also provides a rationale for adding a removable lid as taught by Genatempo. *Id.* at 22–26. Petitioner provides a supporting declaration that is cited and explained as applicable. *See, e.g.*, Pet. 22 (citing Ex. 1037 ¶ 22). We determine that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claim 10 is unpatentable over White, Harding, and Genatempo and, alternatively, over Menyhay and Genatempo.

B. Dependent Claims 11–14

Patent Owner contends that Petitioner's grounds of unpatentability against dependent claims 11–14 are deficient because they do not address the limitations of claim 10 from which they depend. Prelim. Resp. 20–21. Petitioner asserts that claim 10 is unpatentable over White, Harding, and Genatempo (Pet. 4, 21–26), followed by a ground of unpatentability based upon White, Harding, Genatempo, and Paradis (Pet. 4, 26–27, 30–31) that explains how the additional limitation of claim 11 would have been obvious in view of Paradis. For this reason, Patent Owner's argument that the grounds are deficient is unpersuasive.

C. Claim 11

Claim 11 depends from claim 10 and recites, "wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference."

White, Harding, Genatempo, and Paradis

Petitioner contends that claim 11 is unpatentable over White, Harding, Genatempo, and Paradis.¹³ Pet. 4, 26–27, 30–31. Petitioner only identifies a specific portion of Paradis as disclosing threads as claimed. *Id.*

Petitioner's contention that the length of the internal thread of White would have been a matter of design choice would render

¹³ Viewed as a whole, this ground of unpatentability is over White, Harding, Genatempo, and Paradis, so that the omission of Harding and Genatempo from the heading (Pet. 26) is an unimportant distinction. See Pet. 4, 21–27, 29–31.

Paradis superfluous. *See* Pet. 26. The same is true with regard to the contention that it would have been obvious to modify the cap in White to adapt to the external threads of Harding, and the contention that it would be obvious to modify the threads to have the claimed length because it would expose more of the threads to the pad within the cavity to antiseptic. Pet. 26-27 (citing, but not explaining what is contained in Ex. 1037 ¶ 29). This ground of unpatentability is based upon White, Harding, Genatempo, and Paradis, and we will not consider grounds that have not been properly presented. *See* Pet. 4, 26–27, 31 (providing a specific citation to only Paradis with regard to the limitation at issue¹⁴).

Petitioner asserts that Paradis discloses a thread having a length less than the circumference of its cylindrical connector. Pet. 26. Petitioner does not explain cogently how or why a person of ordinary skill in the art would have modified the proposed combination of White, Harding, and Genatempo, to include threads as disclosed by Paradis. Petitioner has the burden to explain how the challenged claim is unpatentable and has not done so sufficiently here. *See* 37 C.F.R. § 42.104(b)(4); *see also Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (obviousness requires more than a showing that the prior art includes separate references covering each limitation of the claims, it must also be shown that a person of ordinary skill in the art would have selected and combined those elements to yield the claimed invention).

¹⁴ *See* 37 C.F.R. § 42.104(b)(5).

Menyhay, Genatempo, and Paradis

Petitioner contends that claim 11 is unpatentable over Menyhay, Genatempo, and Paradis.¹⁵ Pet. 5, 36, 40. Petitioner relies upon Paradis here in a manner that parallels the ground of unpatentability over White, Harding, Genatempo, and Paradis analyzed above. Our analysis there is equally applicable here.

Conclusion

We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 11 is unpatentable over White, Harding, Genatempo, and Paradis or over Menyhay, Genatempo, and Paradis.

D. Claim 12

Claim 12 depends from claim 10 and recites, “wherein the cleaning solution comprises an antimicrobial agent.” Patent Owner presents no arguments against these grounds of unpatentability other than the arguments that we address in sections IV and V.B. above. See Prelim. Resp. 20–22.

White, Harding, and Genatempo, or Menyhay and Genatempo

Petitioner explains how the challenged claim is unpatentable, including specifically alleging where this element is found in White and Menyhay, with citations by exhibit number to the specific portion

¹⁵ Viewed as a whole, this ground of unpatentability is over Menyhay, Genatempo, and Paradis, so that the omission of Genatempo from the heading (Pet. 36) is an unimportant distinction. See Pet. 5, 32–36, 38–40. The same is true with regard to the remaining grounds of unpatentability.

of the evidence that supports the challenge. *See* Pet. 4–5, 27, 31, 36–37, and 40.

Conclusion

We determine that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claim 12 is unpatentable over White, Harding, and Genatempo, and alternatively, over Menyhay and Genatempo.

E. Claim 13

Claim 13 depends from claim 12 and recites, “wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.” Consequently, claim 13 requires the wet pad to be impregnated with either chlorhexidine gluconate or chlorhexidine diacetate.

White, Harding, Genatempo, and Busch

Petitioner contends that claim 13 is unpatentable over White, Harding, Genatempo, and Busch. Pet. 5, 27–28, 30–31. Petitioner acknowledges that White does not disclose an antimicrobial agent as claimed. Pet. 27. Petitioner asserts that it would have been obvious to substitute chlorhexidine gluconate as used in Busch’s skin preparation package for White’s povidone-iodine solution. Pet. 27–28.

White discloses a catheter assembly that includes an outer protective cap 64 that contains a sponge 68 saturated with a disinfectant or antiseptic material that protects the septum of the device from the introduction of pathogens. Ex. 1021, 1:54–55; 6:49–55; 6:67–7:1; Fig. 7. In contrast, Busch does not disclose that skin

preparation package 28 may be utilized to protect a device from the introduction of pathogens; rather, as the name implies, Busch's package 28 contains a solution appropriate for preparing skin for an epidural. Ex. 1026 ¶¶ 11, 26. Petitioner's only evidence that chlorhexidine gluconate and povidone-iodine were known substitutes, is the '864 patent. *See* Pet. 28 (citing Ex. 1002 ¶ 23¹⁶). The portion of the '864 patent cited by Petitioner is not in the *Background* portion of the Specification. Nor does the cited disclosure otherwise indicate that the antimicrobial agents were known substitutes prior to the filing of the application that became the '864 patent.

Consequently, Petitioner has not adequately established that chlorhexidine gluconate as used in Busch's skin preparation package was a known substitute for White's povidone-iodine solution.

Menyhay, Genatempo, and Busch

Petitioner contends that claim 13 is unpatentable over Menyhay, Genatempo, and Busch. Pet. 5, 37, 40–41. Petitioner's ground of unpatentability parallels the ground based upon White, Harding, Genatempo, and Busch, and our analysis there is equally applicable here.

Conclusion

We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 13 is unpatentable over White, Harding, Genatempo, and Busch, or over Menyhay, Genatempo, and Busch.

¹⁶ This is the pre-grant publication of the '864 patent. *See also* Ex. 2001, 2:49–54 (making the same disclosure in the '864 patent).

F. Claim 14

Claim 14 depends from claim 12, and recites, “wherein the cleaning solution is an alcohol-based cleaning solution.”

White, Harding, Genatempo, and Busch

Petitioner contends that claim 14 is unpatentable over White, Harding, Genatempo, and Busch. Pet. 4, 28, 32. Specifically, Petitioner contends that a person of ordinary skill in the art would have substituted Busch’s alcohol-based solution for White’s povidone-iodine. Pet. 28. In addition to the cited disclosure of Busch, Petitioner attempts to support the ground by asserting that a person of ordinary skill in the art would know that it was standard nursing practice to wipe the access port septum with an alcohol wipe prior to accessing the septum. *Id.*

As discussed in section V.E. above, Petitioner has not adequately established the link between use of an agent in a skin preparation package such as disclosed in Busch and use in a device such as White’s. This short-coming is not remedied by Petitioner’s assertion regarding the knowledge of a person of ordinary skill in the art because Petitioner presents only attorney argument, unsupported by evidence. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (Attorney arguments and conclusory statements that are unsupported by factual evidence are entitled to little probative value).

Consequently, Petitioner has not adequately established that isopropyl alcohol as used in Busch’s skin preparation package is a known substitute for White’s povidone-iodine solution.

Menyhay and Genatempo

Petitioner contends that claim 14 is unpatentable over Menyhay and Genatempo. Pet. 5, 37, 41. Specifically, Petitioner asserts that Menyhay discloses use of isopropyl alcohol in the wet pad (sponge 12) of an access valve. Pet. 37, 41. Petitioner explains how the challenged claim is unpatentable, including specifically alleging where each element is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge.

Conclusion

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in establishing that claim 14 is unpatentable over White, Harding, Genatempo, and Busch, but has demonstrated such with regard to Menyhay and Genatempo.

VI. CONCLUSION

For the foregoing reasons, we are persuaded that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claims 10, 12, and 14 of the '864 patent, but not with respect to claims 11 and 13.

The Board has not made a final determination on the patentability of any challenged claims.

VII. ORDER

For the reasons given, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '864 patent is instituted on the following grounds:

A. Claims 10 and 12 under 35 U.S.C. § 103 by White, Harding, and Genatempo; and

B. Claims 10, 12, and 14 under 35 U.S.C. § 103 by Menyhay and Genatempo;

FURTHER ORDERED that no other grounds of unpatentability alleged in the Petition are authorized for this *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial commencing on the entry date of this decision.

PETITIONER:

Michael Kenaga
Sean Swidler
patentmail@iphorgan.net

PATENT OWNER:

David Cavanaugh
Heather Petruzzi
Wilmer Cutler Pickering Hale and Dorr LLP
david.cavanaugh@wilmerhale.com
heather.petruzzi@wilmerhale.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

Case IPR2014-00880
Patent 8,740,864 B2

Before PHILLIP J. KAUFFMAN, HYUN J. JUNG, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

JUDGMENT
Termination of the Proceeding
35 U.S.C. § 317(a) and 37 C.F.R. § 42.72

The parties have requested that this trial be terminated pursuant to a settlement. On December 31, 2014, we authorized the parties via e-mail to file a joint request to terminate this proceeding and to file the settlement agreement as business confidential information under 37 C.F.R. § 42.74(c). The parties filed their motion later that day. Paper 15. With their joint

motion to terminate, the parties also filed a copy of a written settlement agreement that they request be kept confidential. Paper 16, 1; Ex. 1039.¹

Since we instituted a trial in this proceeding on November 25, 2014, the parties have filed no papers other than the joint motion to terminate. Thus, this proceeding is in its initial stages. The parties indicate that they have agreed to resolve all disputes between them related to the challenged patent including the district court litigation matters captioned *Excelsior Medical Corporation, et al v. Becton Dickinson and Company, et al*, 14-cv-03502 (D. N.J.) and *Ivera Medical Corporation and Becton, Dickinson and Company v. Excelsior Medical Corporation, Covidien LP, and Covidien Sales, LLC*, 14-cv-1348 (S.D. Cal.). Paper 15, 1–2. Under these circumstances, we determine that it is appropriate to enter judgment and terminate the trial without rendering a final written decision. 37 C.F.R. § 42.72.

Accordingly, it is

ORDERED that the Joint Motion to Terminate Proceeding under 35 U.S.C. § 317 and 37 C.F.R. § 42.74 is *granted*;

FURTHER ORDERED that the Joint Request to Treat Agreement as Business Confidential Information under 35 U.S.C. § 317 and 37 C.F.R. § 42.74(c), is *granted*.

¹ Papers 15 and 16 in this proceeding do not include page numbering. We refer to page numbers in those papers as if the page immediately following the cover page were enumerated as page 1.

IPR2014-00880
Patent 8,740,864 B2

PETITIONER:

Michael Kenaga
Sean Swindler
IPHORGAN LTD.
patentmail@iphorgan.net

PATENT OWNER:

David Cavanaugh
Heather Petruzzi
WILMER CUTLER PICKERING HALE AND DORR LLP
david.cavanaugh@wilmerhale.com
Heather.Petruzzi@wilmerhale.com



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/281,711	11/17/2005	Minh Quang Hoang	P-6836	9168
71562 7590 04/15/2015 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Kirton & McConkie) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07417-1880			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 04/15/2015	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com



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Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Patent No. 8,740,864
Issue Date: June 3, 2014
Application No. 11/281,711
Filed: November 17, 2005
Attorney Docket No. P-6836

REDETERMINATION
OF PATENT TERM ADJUSTMENT
AND
NOTICE OF INTENT TO ISSUE
CERTIFICATE OF CORRECTION

This is a response to the "REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT" filed July 7, 2014 requesting that the Office adjust the PTA from 1701 days to 1834 days. The Office has re-determined the PTA to be 1834 days.

The petition is **GRANTED**.

This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) that triggers a 180-day period for applicant disagreeing with the Office redetermination to commence a civil action in the District Court for the Eastern District of Virginia.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). The fee set forth in 37 CFR 1.18(e) is a requirement and will not be refunded. No additional fees are required.

Relevant Procedural History

On June 3, 2014, this patent issued with a patent term adjustment determination of 1701 days. On July 7, 2014, patentee timely filed a "REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT", seeking an adjustment of the determination to 1834 days.

Patentee argues "Applicant agrees with the Office's calculation of the patent term adjustment ("PTA") except with regard to the number of B delay days. The calculation of 724 days of B delay correctly identifies the number of days that accrued prior to the filing of an RCE. However, under the Federal Circuit's recent decisions in *Novartis*¹ and *Exelixis*², the B delay should also include each day from the mailing of the notice of allowance until the patent issues. The notice of allowance was mailed on 1/21/2014 and the patent issued on 6/3/2014. Therefore, an additional 133 days should be added to the B delay for this post allowance period. The total B delay is therefore 857 days. Accounting for these additional 133 days yields a total of 1834 days of patent term adjustment. No terminal disclaimer has been filed in this application. Also, the current calculation already accounts for the 171 days of applicant delay that can be considered

Art Unit: OPET

as a failure to engage in reasonable efforts to conclude processing or examination of the application. Applicant therefore respectfully requests that current patent term adjustment be modified to reflect the correct number of 1834 days”.

Upon review, the USPTO finds that patentee is entitled to 1834 days of PTA. The Office has revisited the amount of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

The Office notes that the interpretation of the “B” delay was based upon rule 37 CFR 1.703(b)(1) which excluded from the amount of “B” delay the period beginning on the date of filing of the continued examination and ending on the date of the issuance of the patent. However, subsequent to the filing of this lawsuit and remand to the Office, the Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a Request for Continued Examination (“RCE”) on “B” delay in the *Novartis* appeal. In *Novartis*, the Federal Circuit agreed with the Office that “no [“B” delay] adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing.” *Novartis*, 740 F.3d at 601. However, the *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the “B” delay period but should be counted as “B” delay. *Id.* at 602. The Federal Circuit issued its mandate in the *Novartis* appeal on March 10, 2014.

Pursuant to the *Novartis* decision, the USPTO has determined that the patentee is entitled to 857 days of “B” delay. In this case, the application was filed November 17, 2005, and the patent issued on June 3, 2014; thus, the application was pending for 3121 days. During this time, the applicant filed a first RCE on November 12, 2010. Under 35 U.S.C. § 154(b)(1)(B)(i), the time period consumed by continued examination (“RCE period”) was from November 12, 2010 until the notice of allowance was issued on January 21, 2014 – i.e., 1167 days. Subtracting the sum of the RCE period from the total number of days the application was pending results in $3121 - 1167 = 1954$ days. Thus, for purposes of “B” delay, the application was pending for $1954 - 1097$ [i.e., 3 years from the actual filing date] = 857 days beyond the 3-year anniversary of the filing date.

There is no additional overlap between A and B delay given the additional B delay accorded by this redetermination. The overlap remains 254 days (i.e., November 17, 2008 – July 29, 2009).

Art Unit: OPET

Overall PTA Calculation

Formula:

"A" delay + "B" delay + "C" delay - Overlap - applicant delay = X

USPTO's Calculation:

$$1402 + 857 + 0 - 254 - 171 = 1834$$

Patentee's Calculation

$$1402 + 857 + 0 - 254 - 171 = 1834$$

Conclusion

Patentee is entitled to PTA of one thousand eight hundred thirty-four (1834) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $1402 + 857 + 0 - 254 - 171 = 1834$ days.

Patentee has **two (2) months** from the date of the Office's redetermination of patent term adjustment to request reconsideration of the patent term adjustment if patentee continues to disagree with this determination (no petition fee). This two month period is extendible under 37 CFR 1.136(a). The new/renewed request for reconsideration may be filed without any additional fee. However, patentee who responds more than two months after the mail date of the redetermination is required to pay the extension of time fee. After the period of time to respond has expired, the Office will *sua sponte* issue a certificate of correction adjusting the PTA to one thousand eight hundred thirty-four (1834) days.

Telephone inquiries specific to this decision should be directed to the undersigned Attorney at (571) 272-3212.

/Patricia Faison-Ball/

Patricia Faison-Ball
ATTORNEY ADVISOR
Office of Petitions

Enclosures: Copy of Certificate of Correction
Adjusted PTA calculation

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 8,740,864 B2

DATED : June 3, 2014

INVENTOR(S) : Minh Quang Hoang

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (1701) days

Delete the phrase “by 1701 days” and insert – by 1834 days--

Office of Petitions: Decision Count Sheet

Mailing Month

Application No.

11281711



For US serial numbers: enter number only, no slashes or commas. Ex: 10123456

For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official:

FAISON-BALL, PATRICIA

Count (1) - Palm Credit

11/281,711

Decision: GRANT

FINANCE WORK NEEDED

☐ Select Check Box for YES

Decision Type: 551 - 37 CFR 1.705(d) - PATENT TERM ADJUSTMENT AF



Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED

☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED

☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach
2nd count sheet & mark this box ☐

Printed on: 4/10/2015

Office of Petitions Internal Document - Ver. 5.0

Office of Petitions: Routing Sheet



Application No. 11/281,711

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

☒ **GRANTED**

☐ **DISMISSED**

☐ **DENIED**

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 11/281,711

Filing or 371(c) Date:	11-17-2005	Overlapping Days Between { A and B} or { A and C} :	254
Issue Date of Patent:	06-03-2014	Non-Overlapping USPTO Delays:	1872
A Delays:	1402	PTO Manual Adjustments:	133
B Delays:	724	Applicant Delays:	171
C Delays:	0	Total PTA Adjustments:	1834

Patent Term Adjustment History		Explanation Of Calculations			
Number	Date	Contents Description	PTO(Days)	APPL(Days)	Start
117	04-10-2015	Adjustment of PTA Calculation by PTO	857		0
117	04-10-2015	Adjustment of PTA Calculation by PTO	857		0
116	04-10-2015	Adjustment of PTA Calculation by PTO		724	0
116	04-10-2015	Adjustment of PTA Calculation by PTO		724	0
109.5	11-11-2010	PTA 36 Months	724		0.5
109	06-03-2014	Patent Issue Date Used in PTA Calculation			0
108	05-02-2014	Export to Final Data Capture			0
107	05-01-2014	Dispatch to FDC			0
106	05-01-2014	Application Is Considered Ready for Issue			0
105	04-21-2014	Issue Fee Payment Verified			0
104	04-21-2014	Issue Fee Payment Received			0
103	04-07-2014	Mail Interview Summary - Applicant Initiated - Telephonic			0
102	04-02-2014	Office Action Review			0
101	04-02-2014	Office Action Review			0
100	04-02-2014	Office Action Review			0
99	04-01-2014	Interview Summary- Applicant Initiated			0
98	04-01-2014	Interview Summary - Applicant Initiated - Telephonic			0
97	02-26-2014	Finished Initial Data Capture			0
96	01-20-2014	Export to Initial Data Capture			0
95	01-21-2014	Electronic Review			0
94	01-21-2014	Email Notification			0
	01-21-				

93	2014	Mail Notice of Allowance		0
92	01-15-2014	Office Action Review		0
91	01-15-2014	Office Action Review		0
90	01-15-2014	Office Action Review		0
89	01-15-2014	Office Action Review		0
88	01-15-2014	Office Action Review		0
87	01-15-2014	Issue Revision Completed		0
86	01-15-2014	Document Verification		0
85	01-15-2014	Notice of Allowance Data Verification Completed		0
84	01-13-2014	Reasons for Allowance		0
83	01-13-2014	Examiner's Amendment Communication		0
82	01-13-2014	Interview Summary - Examiner Initiated - Telephonic		0
81	01-13-2014	Interview Summary - Examiner Initiated		0
80	01-13-2014	Allowability Notice		0
79	11-14-2013	Information Disclosure Statement considered		0
78	11-15-2013	Date Forwarded to Examiner		0
77	11-14-2013	Response after Non-Final Action		0
76	11-14-2013	Incoming Letter Pertaining to the Drawings		0
75	11-14-2013	Electronic Information Disclosure Statement		0
74	11-14-2013	Information Disclosure Statement (IDS) Filed		0
73	08-15-2013	Electronic Review		0
72	08-15-2013	Email Notification		0
71	08-15-2013	Mail Non-Final Rejection	83	61
70	08-12-2013	Office Action Review		0
69	08-12-2013	Office Action Review		0
68	08-08-2013	Interview Summary- Applicant Initiated		0
67	08-09-2013	Non-Final Rejection		0
66	04-16-2013	Information Disclosure Statement considered		0

65	04-16-2013	Electronic Information Disclosure Statement	82	61
64	04-16-2013	Information Disclosure Statement (IDS) Filed		0
63	01-28-2013	Date Forwarded to Examiner		0
62	01-24-2013	Amendment Submitted/ Entered with Filing of CPA/ RCE		0
61	01-24-2013	Request for Continued Examination (RCE)	29	51
60	01-28-2013	Disposal for a RCE / CPA / R129		0
59	01-24-2013	Workflow - Request for RCE - Begin		0
58	01-23-2013	Mail Interview Summary - Applicant Initiated - Telephonic		0
57	01-16-2013	Office Action Review		0
56	01-16-2013	Office Action Review		0
55	01-15-2013	Interview Summary- Applicant Initiated		0
54	01-15-2013	Interview Summary - Applicant Initiated - Telephonic		0
53	09-26-2012	Electronic Review		0
52	09-25-2012	Email Notification		0
51	09-25-2012	Mail Final Rejection (PTOL - 326)		0
50	09-20-2012	Office Action Review		0
49	09-19-2012	Final Rejection		0
48	07-03-2012	Date Forwarded to Examiner		0
47	06-28-2012	Response after Non-Final Action		0
46	05-30-2012	Mail Applicant Initiated Interview Summary		0
45	05-29-2012	Office Action Review		0
44	05-24-2012	Interview Summary- Applicant Initiated		0
43	04-10-2012	Mail Non-Final Rejection	395	32
42	04-09-2012	Office Action Review		0
41	04-05-2012	Non-Final Rejection		0
40	02-16-2012	Change in Power of Attorney (May Include Associate POA)		0
39	02-14-2012	Correspondence Address Change		0
38	05-19-2011	Not Inherited		0

37	05-19-2011	Case Docketed to Examiner in GAU		0
36	05-17-2011	case Inherited		0
35	05-17-2011	Case Docketed to Examiner in GAU		0
34	11-29-2010	Date Forwarded to Examiner		0
33	11-12-2010	Amendment Submitted/Entered with Filing of CPA/RCE		0
32	11-12-2010	Request for Continued Examination (RCE)	60	26
31	11-29-2010	Disposal for a RCE / CPA / R129		0
30	11-12-2010	Request for Extension of Time - Granted		0
29	11-12-2010	Workflow - Request for RCE - Begin		0
28	09-13-2010	Mail Examiner Interview Summary (PTOL - 413)		0
27	09-09-2010	Examiner Interview Summary Record (PTOL - 413)		0
26	06-11-2010	Mail Final Rejection (PTOL - 326)		0
25	06-09-2010	Final Rejection		0
24	04-09-2010	Date Forwarded to Examiner		0
23	02-19-2010	Response after Non-Final Action		0
22	11-25-2009	Mail Non-Final Rejection		0
21	11-23-2009	Non-Final Rejection		0
17	10-07-2009	Date Forwarded to Examiner		0
16	08-24-2009	Response to Election / Restriction Filed		0
14	07-29-2009	Mail Restriction Requirement	924	0.5
13	07-28-2009	Restriction/Election Requirement		0
12	11-28-2007	Case Docketed to Examiner in GAU		0
11	05-17-2007	PG-Pub Issue Notification		0
10	08-18-2006	IFW TSS Processing by Tech Center Complete		0
9	02-03-2006	Correspondence Address Change		0
8	12-21-2005	Application Return from OIPE		0
7	12-22-2005	Application Is Now Complete		0
6	12-21-	Application Return TO OIPE		0

	2005		
5	12-20-2005	Application Dispatched from OIPE	0
4	12-21-2005	Application Is Now Complete	0
3	12-12-2005	Cleared by OIPE CSR	0
2	11-25-2005	IFW Scan & PACR Auto Security Review	0
1	11-17-2005	Initial Exam Team nn	0
0.5	11-17-2005	Filing date	0

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To:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Southern District of California on the following: X Patents or Trademarks:

DOCKET NO.	DATE FILED	US District Court Southern District of California
3:14-cv-01348-GPC-JLB	6/3/14	San Diego, CA
PLAINTIFF		DEFENDANT
Ivera Medical Corporation, et al.		Excelsior Medical Corporation, et al.
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.
1. 8,740,864	6.	11.
2.	7.	12.
3.	8.	13.
4.	9.	14.
5.	10.	15.

In the above-entitled case, the following patents(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY	
	<u> </u> Amendment <u> </u> Answer <u> </u> Cross Bill <u> </u> Other Pleading	
PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.	PATENT OR TRADEMARK NO.
1.	6.	11.
2.	7.	12.
3.	8.	13.
4.	9.	14.
5.	10.	15.

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT	Order Granting Joint Motion to Dismiss

CLERK	(BY) DEPUTY CLERK	DATE
John Morrill, Clerk of Court	A. Garcia	04/15/2015

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,740,864 B2
APPLICATION NO. : 11/281711
DATED : June 3, 2014
INVENTOR(S) : Hoang et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b)
by 1834 days.

Signed and Sealed this
Thirtieth Day of May, 2017

A handwritten signature in black ink, reading "Michelle K. Lee". The signature is written in a cursive, flowing style.

Michelle K. Lee
Director of the United States Patent and Trademark Office