

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION,

Petitioner,

v.

BECTON, DICKINSON AND COMPANY,

Patent Owner

Patent No. 8,740,864

Issued : June 3, 2014

Title: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL
CAP/CLEANER

Trial No.: Unassigned

PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.*

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List of Exhibits

Petitioner Exhibit No.	Exhibit
Ex. 1001	Issue Notification for U.S. Patent No. 8,740,864
Ex. 1002	U.S. Patent Publication 2007/0112333 to Hoang for "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner"
Ex. 1003	U.S. Divisional Patent No. 8,491,546 to Hoang for "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner"
Ex. 1004	Requirement for Restriction/Election mailed July 29, 2009
Ex. 1005	Restriction Response filed August 24, 2009
Ex. 1006	Non-Final (First) office action mailed November 25, 2009
Ex. 1007	"Amendment A" filed February 19, 2010
Ex. 1008	Final (Second) office action mailed June 11, 2010
Ex. 1009	"Amendment B" filed November 12, 2010
Ex. 1010	Non-final (Third) office action mailed April 10, 2012
Ex. 1011	Applicant Initiated Interview Summary May 30, 2012
Ex. 1012	"Amendment C" filed June 28, 2012
Ex. 1013	Final (Fourth) office action mailed September 25, 2012
Ex. 1014	Applicant Initiated Interview Summary January 23, 2013
Ex. 1015	"Amendment D" filed January 24, 2013
Ex. 1016	Applicant Initiated Interview Summary August 15, 2013
Ex. 1017	Non-final (Fifth) office action mailed August 15, 2013
Ex. 1018	"Amendment E" filed November 14, 2013
Ex. 1019	Examiner Initiated Interview Summary January 21, 2014
Ex. 1020	Applicant Initiated Interview Summary April 7, 2014
Ex. 1021	WHITE, U.S. Patent No. 5,242,425
Ex. 1022	HARDING 2003, U.S. Patent Publication No. 2003/009853
Ex. 1023	HARDING 2008, U.S. Patent Publication No. 2008/0027399
Ex. 1024	GENATEMPO, U.S. Patent No. 4,440,207
Ex. 1025	PARADIS, U.S. Patent No. 6,117,114
Ex. 1026	BUSCH, U.S. Patent Publication No. 2004/0004019
Ex. 1027	LAKE, U.S. Patent Publication No. 2004/0258560
Ex. 1028	PELUSO, U.S. Patent No. 4,624,664
Ex. 1029	MENYHAY, U.S. Patent No. 5,554,135
Ex. 1030	LYNN, U.S. Patent Publication No. 2002/0193752

Ex. 1031	35 U.S.C. 103(a) as effective prior to March 16, 2013
Ex. 1032	<i>KSR Int'l v. Teleflex Inc.</i> , 550 U.S. 398 (2007)
Ex. 1033	<i>Philips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)
Ex. 1034	<i>Graham v. John Deere</i> , 381 U.S. 1 (1966)
Ex. 1035	<i>In re Bigio</i> , 381 F.3d 1320 (Fed. Cir. 2004)
Ex. 1036	<i>Okajima v. Bourdeau</i> , 261 f.3d 1350 (Fed. Cir. 2001)
Ex. 1037	Declaration of Terry Layton, Ph.D.

I. INTRODUCTION

Petitioner seeks *inter partes* review of claims 10 to 14 of U.S. Patent No. 8,740,864 (the "'864 patent"), which issued on June 3, 2014, to Becton, Dickinson and Company ("Patent Owner"). Petitioner relies on new prior art -- U.S. Publication No. 2003/0109853 to Harding, et al. (Ex. 1022) -- that was not before the examiner during the prosecution of the '864 patent. In addition, Petitioner shows that the examiner did not fully appreciate the disclosures of the primary references during prosecution, including U.S. Patent No. 5,242,425 to White (Ex. 1021), and U.S. Patent No. 4,440,207 to Genatempo (Ex. 1024).

II. MANDATORY NOTICES

A. Real Party-In-Interest

Petitioner Excelsior Medical Corporation is the real party-in-interest.

B. Related Matters

Petitioner is filing, concurrent with this petition, a declaratory judgment action in the District of New Jersey against Patent Owner and its exclusive licensee, Ivera Medical Corporation, entitled *Excelsior Medical Corporation v. Becton, Dickinson and Company, et al.* There are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

C. Lead and Back-Up Counsel

Petitioner is represented by Michael L. Kenaga (Reg. No. 34,639) as lead counsel, and Sean S. Swidler (Reg. No. 49,033) as back-up counsel. The addresses for both are:

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D. Power of Attorney

Petitioner submits herewith a power of attorney in favor of the lead and back-up counsel identified above.

E. Service Information

The service information for Petitioner required under §42.8(b)(4)(i-v) is set out above under the designation of lead and back-up counsel. Electronic service is approved and preferred.

III. PETITION FEE

The undersigned authorizes the Office to charge \$23,000.00 to Deposit Account No. 50-3993 in payment of the fee required under §42.15(a)(1) for filing a request for *inter partes* review, and under §42.15(a)(2) for *inter partes* review post-institution. Petitioner submits that the fees required by §42.15(a)(3) and

§42.15(a)(4) are not applicable because this Petition seeks review of only five claims.

IV. GROUNDS FOR STANDING

As required under §42.104(a), Petitioner certifies that the '864 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting such review on the grounds identified in this Petition.

V. RELIEF REQUESTED

A. Statement of Precise Relief Requested

As required by §42.22(a)(1) and §42.104(b), Petitioner asks the Board to initiate *inter partes* review on challenged claims 10 to 14 of the '864 patent on all grounds of unpatentability asserted against each claim, and to cancel claims 10 to 14.

B. Full Statement of Reasons for the Relief Requested

Petitioner provides a full statement of the reasons for the relief requested, including a detailed explanation of the significance of the material facts and governing law, below.

VI. CLAIMS CHALLENGED ON THE BASIS OF SPECIFIC PRIOR ART

As required by §42.22(a)(1-2) and §42.104(b)(1-2), Petitioner challenges the claims in issue as obvious under 35 U.S.C. 103(a) (pre-AIA) on the basis of the following prior art combinations:

- A. Claim 10 -- White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- B. Claim 11 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- C. Claim 12 -- White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- D. Claim 13 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- E. Claim 14 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- F. Claim 10 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).
- G. Claim 11 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- H. Claim 12 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).
- I. Claim 13 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Busch (Ex. 1026).
- J. Claim 14 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).

VII. THE '864 PATENT

A. Overview of the '864 Patent

The '864 patent issued on June 3, 2014, from an application, serial no. 11/281,711, filed on November 17, 2005.

The '864 patent is directed to an antimicrobial cap for a patient fluid line (catheter) access valve that is left in a patient's body during an extended treatment regimen. The access valve contains a septum into which a male luer (or needle) is inserted to administer medicine or other liquids to a patient through a catheter. The disinfecting cap is placed over the access valve when the patient is not being treated to prevent bacterial contamination of the access valve that could cause infections and other maladies. (See Abstract, and the sixth paragraph of the Detailed Description).

Claims 10 to 14 provide:

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;

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.

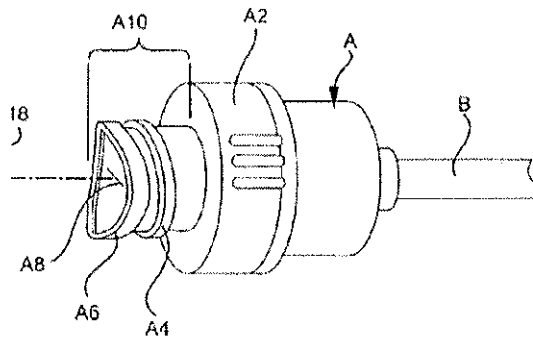
11. The device of claim 10, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

12. The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.

13. The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

14. The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.

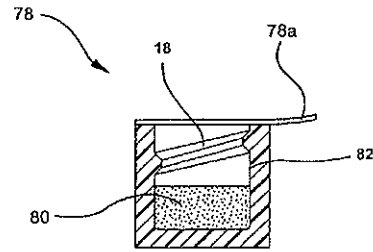
Hence, the preamble of claim 10 calls for a protective cap for an "access portion" of an access valve with "an end face that includes a septum and external threads . . . proximate the septum." The access portion, septum, and threads of the access valve of claim 10 are illustrated below in the partial reproduction of Figure 1 (and described in the associated text) of the '864 patent as items A6 (septum), A4 (thread), and A10 (access portion).



7. The subsequent limitations of claim 10 require:

(i) a cap 78 with threads 18 on the inner wall of the cavity of the cap to engage the external threads [A4] of the access portion [A10] of the access valve [A];

FIG. 10B



(ii) a "wet pad [80] impregnated with a cleaning solution" in the cavity "for contacting the end face [of the septum A6 of fig. 1] ...and at least a portion of the external threads [A4] of the access portion" of the access valve; and

(iii) a removable lid 78A over the open end of the cap to protect the wet pad until the lid is removed and the cap is attached to access valve "so that the end face of the access portion contacts the wet pad."

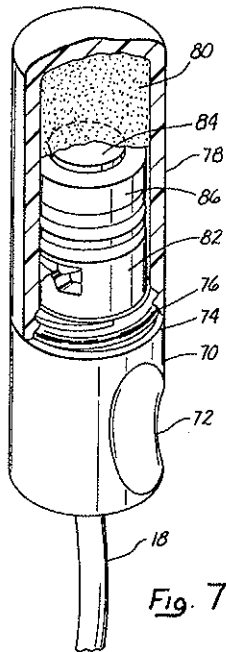
8. Dependent claim 11 calls for the cavity of the cap to have an inner circumference 82 with a thread 18 that comprises a length that is less than the inner circumference. Dependent claim 12 specifies that the cleaning solution of claim 10 is an antimicrobial agent. Dependent claim 13, in turn, requires the antimicrobial agent of claim 12 to be at least one of chlorhexidine gluconate and chlorhexidine diacetate. Lastly, dependent claim 14 calls for the cleaning solution of claim 10 to be an alcohol-based cleaning solution.

B. The Prior Art

1. The White Patent

United States Patent No. 5,242,425 to White, et al. (Ex. 1021, "White" or the "White patent") issued in 1993. White shows that the use of catheter access valves long pre-dates the 2005 filing of the Hoang patent application, and that it has been well known for almost as long that patients run a high risk of infection if an access valve is not properly maintained to prevent contamination by bacteria. (Ex. 1021, col. 2, lines 27-34). The White patent discloses an answer to the contamination/infection problem in the form of a cap, containing a sponge with a disinfecting solution, that is placed over a catheter access valve when it is not being used to treat a patient.

More specifically, as shown in Figure 7 and described in the associated text of the White patent, an outer protective cap 78 contains a sponge 80 saturated with an antiseptic. The cap 78 has internal threads 76 at the open, distal end. The protective cap fits on a catheter coupler (or access) assembly 70, 82 with a self-sealing septum 84, injection cap 82, and external shoulder threads 74 to receive the internal threads 76 of the protective cap 78.



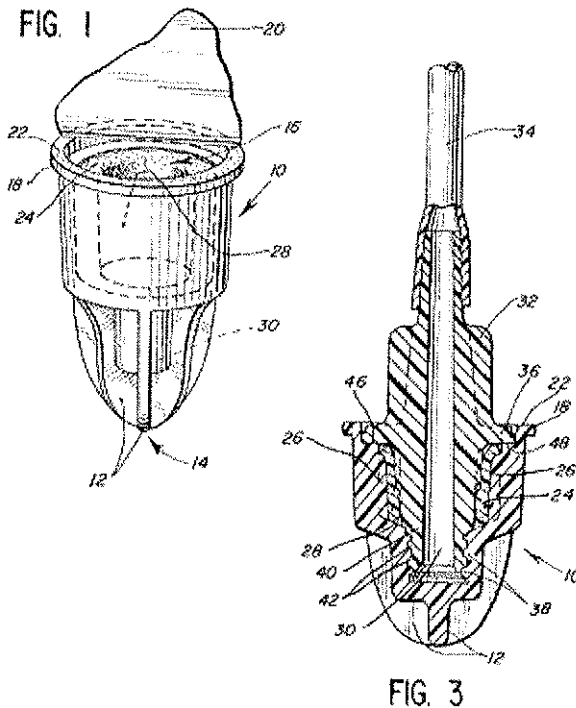
The protective cap 78 is spaced from the injection cap 82 "to permit antiseptic to bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84" when the cap is placed on the access valve assembly 70. (Ex. 1021, col. 7, lines 29-32).

White also discloses in another embodiment in Figs. 1-6 an outer protective cap 64 having a sponge 68 saturated with an antiseptic material. The cap 64 does not include threads but rather snap-fits onto a catheter coupler 10, 32 having a septum 54.

2. The Genatempo Patent

United States Patent No. 4,440,207 to Genatempo, et al. (Ex. 1024, "Genatempo" or the "Genatempo patent"), issued in 1984. As seen in Figs. 1 and 3 shown below, Genatempo also discloses a protective cap 10 containing absorbent

material 24 saturated with antiseptic liquid that is placed in contact with a connector 32 attached to medical tubing 34, such as a catheter, to prevent contamination of the connector 32 before or between uses. (See Ex. 1024, col. 2, lines 66-68 and col. 3, lines 22, 23, 32-35, 40 and 41).



A removable, peel-back, lid 20 covers the open end of the cap 10 to prevent loss of the antiseptic liquid prior to use. In addition, the internal wall of the cap has threads 38 to engage the external threads 42 of a connector 32. As shown in Figure 3 and described in the specification of the Genatempo patent, when the cap is placed on a connector "an antibacterial effect" is provided to the connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, col. 3, lines 43-45).

3. The Harding Publication

U. S. Publication No. 2003/0109853 to Harding, et al. (Ex. 1022, "Harding" or the "Harding publication"), was published on June 12, 2003. The Patent Owner was the assignee of Harding at the time of filing and publication, but did not disclose the Harding publication or its subject matter to the examiner during prosecution of the '864 patent.

Harding discloses a catheter access valve that is remarkably similar, if not identical, to the access valve depicted in Figure 1 of the '864, as illustrated by, for example, the access valves of Figure 4 of Harding and part of Figure 1 of the '864 patent:

FIG. 4

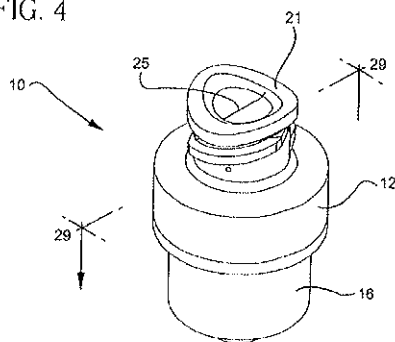
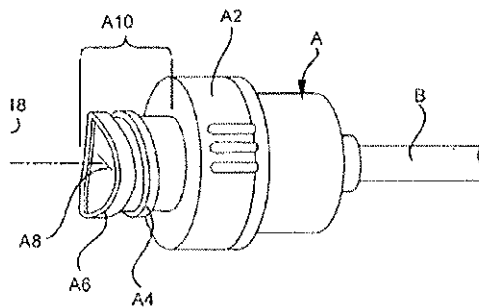


FIG. 4 of HARDING



PART OF FIG. 1 OF '864 PATENT

The Harding access valve 10 includes a top portion 12 that contains a septum 20 and has exterior luer threads 14 adjacent the septum "that allow another

medical device having a male luer lock to be connected to the top of proximal portion 12." (Ex. 1022, paragraph [0073]).

4. The Paradis Patent

U. S. Patent No. 6,117,114 to Paradis (Ex. 1025, the "Paradis patent"), issued in 2000, teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).

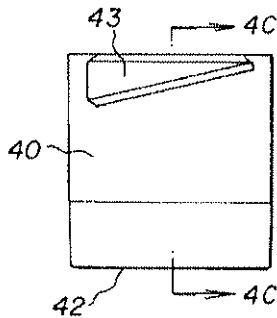


Fig. 4A

5. The Busch Patent

U. S. Publication No. 2004/0004019 to Busch, was published on January 8, 2004 (Ex. 1026, "Busch" or the "Busch publication"). It discloses "a presoaked preparation swab, sponge, applicator, or the like" that is saturated with antiseptic liquid and used to prevent contamination. The cleaning solution may be "[b]etadine or another antiseptic solution (e.g. alcohols, iodophors, chlorhexadine, chlorhexadine gluconate with isopropyl alcohol, etc.)." (Ex. 1026, paragraph [0026]).

6. The Menyhay Patent

U.S. Patent No. 5,554,135 to Menyhay issued September 10, 1996. (Ex. 1029). It discloses in Fig. 2 (reproduced below) an external injector port 19, with an access portion having external threads 17, and an end face having a septum 18. A catheter 25 extends from the port 19. A cover 10 is shown having an open end and a closed end, forming a cavity (Fig. 2). An internal wall of the cover 10 includes internal threads 15. The closed end includes an inwardly pointed projection 13. The cover 10 receives the breakable capsule 11 and sponge 12. The breakable capsule 11 includes an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol. Ex. 1029, col. 6, lines 44-58.

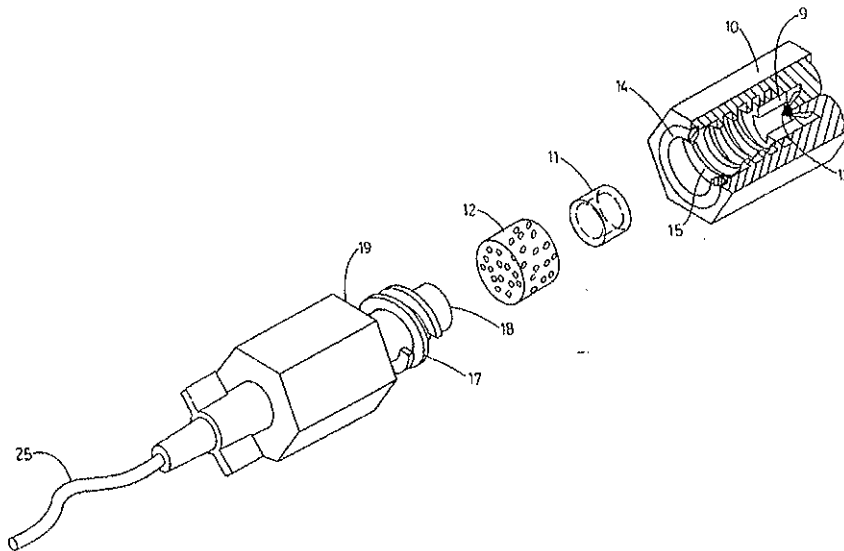


Fig. 2 of Menyhay

C. **Summary of Prosecution of the '864 Patent**

Although the application for the '864 was filed in 2005, the first office action did not occur until July 2009 when the examiner issued a restriction requirement because the original application claims covered a combination cleaner and cap 10 (see, e.g., Figures 1-4, 6-9) as well as the independent, standalone disinfecting cap 78 of Figure 10B. See Restriction mailed July 29, 2009 (Ex. 1004). The patent owner elected to proceed with the cap alone.¹

The examiner issued five substantive rejections of claims proposed by the Patent Owner throughout prosecution of the '864 application in view of, among other references, White, Genatempo, Paradis, and Busch. Finally, in the fifth office action on the merits of August 15, 2013 (Ex. 1017), the examiner indicated that, upon curing an antecedent basis rejection, new dependent application claim 71 would be allowable because it provided that the internal threads of the cap "receive[] the external threads thereby causing the interface to advance into the inner cavity such that the septum contacts the wet pad."

The examiner otherwise rejected application claim 79 (now issued claim 10) in the fifth office action as obvious because White disclosed all the features of

¹ The Patent Owner filed a divisional application covering the combination cleaner and cap, which issued as U.S. Patent No. 8,491,546 on July 23, 2013 (Ex. 1003).

claim 79 except for a lid, and that Genatempo disclosed the lid missing from White. Dependent application claims 80 to 83 were rejected in light of combinations of White, Genatempo, Paradis, and Busch.

In response to the fifth office action, the Patent Owner cancelled application claim 71 and amended independent application claims 69 and 84 (now, issued claims 1 and 15) to require rotation of the internal threads of the cap with the external threads of the access valve to cause the wet pad to come into contact with the septum.

However, the Patent Owner did not amend claim 79 to include such a rotational limitation. Instead, claim 79 was simply amended to require that the wet pad "disinfect[] the end face and a portion of the external threads" of the access valve.

With a minor, irrelevant change, the examiner allowed application claims 69, 70, and 72 to 88, as so amended, on January 21, 2014. In his reasons for allowance, the examiner cited the rotational limitations added to application claims 69 and 84:

The prior art does not disclose or render obvious the combination as claimed specifically including housing have 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.

See Examiner's Statement of Reasons for Allowance (Ex. 1019, pages 7 and 8).

Forgetting about White, the examiner wrongly determined that Genatempo was the closest prior art, finding that "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 [sic] the wet pad and is no longer in contact." That is a correct description of Genatempo as its Figure 3 shows that the end face near reference arrow 42 is located in cavity 30 below the wet pad 24.

In a subsequent interview initiated by the Patent Owner on April 1, 2014, the examiner acknowledged that application claim 79 does not require rotational movement of the cap and that it is enough that the housing wet pad engage the access portion. The examiner again noted Genatempo does not teach or suggest that the end face of a septum comes into contact with a pad as discussed above. See Applicant Initiated Interview Summary, (Ex. 1020, p.4). White was not discussed. (Ex. 1020, p. 2).

VIII. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Claim Construction

As required by §42.22(a)(2) and §42.104(b)(3), Petitioner submits that the claim terms of issued claims 10-14 are to be given their broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the disclosure.

B. Ordinary Skill in the Art

Petitioner submits that the relevant person of ordinary skill in the art includes one skilled in the art of patient fluid line access valve antimicrobial caps. Examples of such persons skilled in the art prior to the filing date of November 17, 2005 of the underlying application, may be inferred from the following prior art.

Patent Publication No.	Exhibit No.
WHITE, U.S. Patent No. 5,242, 425	Ex. 1021
HARDING 2003, U.S. Patent Publication No. 2003/009853	Ex. 1022
HARDING 2008, U.S. Patent Publication No. 2008/0027399	Ex. 1023
GENATEMPO, U.S. Patent No. 4,440,207	Ex. 1024
PARADIS, U.S. Patent No. 6,117,114	Ex. 1025
BUSCH, U.S. Patent Publication No. 2004/0004019	Ex. 1026
LAKE, U.S. Patent Publication No. 2004/0258560	Ex. 1027
PELUSO, U.S. Patent No. 4,624,664	Ex. 1028
MENYHAY, U.S. Patent No. 5,554,135	Ex. 1029

C. The Obviousness Framework

An invention that would have been obvious to a person having ordinary skill in the relevant art is not patentable. 35 U.S.C. §103(a) (pre-AIA). (Ex. 1031, p. 1) As established in *Graham v. John Deere Co.*, 383 U.S. 1, ___ (1966), obviousness is a question of law that is resolved, in part relevant here, in light of following factual inquiries: (i) the scope and content of the prior art; (ii) the level of ordinary skill in the art; and (iii) the differences between the between the claimed invention and the prior art. Based on those factual inquiries, the focus in determining obviousness is on what a person of ordinary skill in the relevant art would have known at the time of the invention and on what that person would have been able to do with that knowledge. M.P.E.P. § 2141(II).

The scope and content of the prior art has been detailed above. The cited references are plainly relevant as they are from the same field of endeavor as the claimed inventions and are pertinent to the problem confronting the inventor. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). (Ex. 1035).

Petitioner submits that the level of skill of the hypothetical person of ordinary skill in the art may be inferred from the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). (Ex. 1036). Alternatively, petitioner's expert, Dr. Terry Layton, opines that a person of ordinary skill would have a bachelor's degree in biomechanical or mechanical engineering and a

minimum of two to three years of work experience in the development and design of medical devices that connect to catheters or tubes where bacterial contamination may be an issue. Layton Dec., ¶ 20.

Petitioner discusses immediately below the differences between the prior art and the subject matter of claims 10 to 14, giving the claims "the broadest reasonable interpretation consistent with the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). (Ex. 1033).

D. Claim 10 Is Obvious in View of White, Harding, and Genatempo

Several substantial limitations of claim 10 of the '864 patent are disclosed by the White patent. Both White and claim 10 describe a disinfecting cap for an indwelling catheter access valve. (Ex. 1021, col. 2, lines 53-61). Each cap contains a sponge that is saturated with an aseptic solution, and each cap has internal threads for mating with the external threads of a catheter access valve. (Ex. 1021, col. 7, lines 26-29). Upon positioning the caps of White and claim 10 on an access valve, the sponges in both caps come into contact with a septum and disperse aseptic solutions that bathe the septum and the surrounding structure of the access valve to prevent bacterial contamination. (Ex. 1021, col. 7, lines 29-32). Layton Dec. Ex. 1037, ¶ 22.

White and claim 10 differ in only three minor respects: namely, as to the location of the external threads of the access valve of White; whether the aseptic solution of White disinfects a portion of the external threads; and the absence of an express teaching of a peel-able lid on White's protective cap. The solution to these differences would have been readily obvious to a person of ordinary skill, given his or her's presumed knowledge of the teachings of the prior art Harding publication and Genatempo patent, as well as the inherent properties of the White cap.

First, White may not meet the limitation of the preamble of claim 10, requiring that the external threads of the access valve be "proximate" the septum, because the external threads 74 of the access valve of White are near the shoulder of the valve. (Ex. 1021, col. 7, lines 23-25).

However, one of ordinary skill in the art would have known that the Harding publication discloses an access valve with external threads near the septum that is very similar, if not identical, to the access valve of the '864 patent and claim 10. Layton Dec. Ex. 1037, ¶ 23. Hence, charged with the task of designing a disinfecting cap for an access valve with threads near the septum, it would have been an utterly predictable and simple matter for a person of ordinary skill to relocate the internal threads of the White cap away from the opening so that, when placed on access valve with external threads near a septum as disclosed in Harding, the sponge of the White cap would make contact with the septum to cause the

disinfectant to bath the septum and surrounding area. Layton Dec. Ex. 1037, ¶ 23. Thus, modifying the protective cap 78 of White to adapt to the access connector of Harding would provide the identical arrangement as recited by the preamble of claim 10. KSR, 550 U.S. 398, 417 (2007) ("If a person of ordinary skill can implement a predictable variation, and would see the benefit of doing so, §103 likely bars [an invention's] patentability.")

Second, White does not explicitly disclose that the aseptic solution in the sponge of the cap will contact "at least a portion of the external threads of the access portion" of the access valve, as specified by claim 10. This gap is amply filled by the Genatempo patent's express disclosure of a disinfecting cap similar to White that, when placed on a connector, provides "an antibacterial effect" to the connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, col. 3, lines 43-45). One skilled in the art would readily be motivated to ensure that the arrangement of White would similarly provide such antibacterial effect to the external threads 74 of White in modifying White to accommodate the access connector of Harding.

Moreover, the person of ordinary skill would understand that the aseptic solution would also flow onto at least a portion of the external threads of the access valve given White's disclosures that:

"the antiseptic material is *forced* within a space between proximal member 10 (sic, "32") and outer protective cap 64 (Ex. 1021, col. 6, lines 60-63),"

and that

"[t]he outer protective cap 78 [of Figure 7] is spaced from proximal member or injection cap 82 to permit antiseptic to bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84 (Ex. 1021, col. 7, lines 29-32.

Layton Dec. Ex. 1037, ¶ 25-28. Still further, adapting the cap 78 of White to engage the external threads near the septum of the access valve of Harding will result in the sponge 80 being closer to the external threads. Thus, increasing the likelihood of the solution of White to disinfect at least a portion of the external threads.

It is also worth noting that the Patent Owner did not introduce a limitation requiring the disinfecting solution to contact the external threads of the access valve to the independent claims of the '864 application until January 2013. There is *no* disclosure in the written description of the '864 patent to support that limitation. Thus, a serious question exists as to whether this limitation would run afoul of the written description requirement of Section 112, unless it is inherent in the interface of the sponge of the disinfecting cap and the access valve septum that

the disinfecting solution will reach the external threads. If that result is inherent in claim 10 of the '864 patent, it must also be inherent when the cap of White is placed on an access valve septum.

Third, White does not explicitly disclose a removable lid over the end of the disinfecting cap that engages the access valve to protect the aseptic solution prior to placing the cap on an access valve, as required by claim 10.² But the use of a lid to preserve the solution in the White sponge would have been obvious to one of ordinary skill in view of the Genatempo patent's disclosure of just such a lid for that purpose. Indeed, it is inconceivable, as basic matters of hygiene and commerce, that a product embodying the White patent's cap in the 1990s, or at any time prior to the 2005 filing date of the Hoang patent application, would not have a protective lid or cover during shipment, storage and prior to use. Layton Dec. Ex. 1037, ¶ 24.

Hence, claim 10 is obvious in view of White, Harding, and Genatempo.

E. Claim 11 Is Obvious in Light of White and Paradis

² White does, however, disclose at col. 3, lines 51-55, that after removal of the outer protective cap 78, a preferably fresh new outer protective cap 78 is placed on the coupler. The new cap 78 apparently includes a lid or is placed in a package in order to maintain a sterile nature prior to its use.

Both White and claim 11 of the '846 patent disclose a cavity having an inner circumference and a thread having a length. It is not clear whether the length of the internal thread of White is less than the inner circumference. However, this is a trivial difference because a person of ordinary skill in the art would understand that this is a mere design choice dependent on the type of valve to which the cap is attached. It would be obvious for one of ordinary skill in the art to modify the cap in White to have a thread length less than an inner circumference in order to adapt to the external threads of the Harding publication, which appears to be the valve to which the '846 patent is adapted. Further, the Paradis patent teaches a valve with threading of a length that is less than the circumference of cylindrical connector. See partial luer threads 43 in Fig. 4a. (Ex. 1025, p. 5). See also the Examiner's similar rejection of application claim 80 on the basis of Paradis (Ex. 1017, page 17). Finally, see Layton Dec. Ex. 1037, ¶ 29.

F. Claim 12 Is Obvious in Light of White and Harding

Claim 12 of the '846 patent calls for the cleaning solution of claim 10 to be an "antimicrobial agent." White discloses an antiseptic such as a povidone-iodine solution to keep the septum free of pathogens. One of ordinary skill in the art would recognize that a povidone-iodine solution is as an antimicrobial agent. In fact, the '846 patent identifies povidone iodine as an example of an antimicrobial

agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

G. Claim 13 Is Obvious in light of White, Harding, Genatempo and Busch

Claim 13 of the '846 requires an antimicrobial agent comprised of at least one of chlorhexidine gluconate or chlorhexidine diacetate. White does not specifically disclose the use of chlorhexidine gluconate or chlorhexidine diacetate. However, it would have been obvious to one of ordinary skill to substitute a chlorhexidine gluconate for White's use of a povidone-iodine solution in view of the Busch publication's disclosure of a skin preparation package including chlorhexidine gluconate as an antiseptic solution. Moreover, one having ordinary skill in the art would have seen chlorhexidine diacetate as an obvious substitute for povidone iodine because the '846 patent discloses that "[a]ny number of microbial agents may be used" including "chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chlorizde, octenidine, antibiotic, etc." Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).

H. Claim 14 Is Obvious in Light of White, Harding, Genatempo and Busch

Claim 14 of the '846 patent requires an alcohol-based cleaning solution.

While White's povidone iodine solution is not alcohol-based, it would have been obvious to one of ordinary skill in the art to substitute an alcohol-based solution for povidone iodine in view of Busch's disclosure of isopropyl alcohol as an antiseptic solution. In addition, one skilled in the art would know that it was standard nursing practice, prior to the advent of protective caps, to wipe the access port septum with an alcohol wipe prior to accessing the septum.

I. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of the comments above.

CLAIM 10	
White, Harding, and Genatempo	
CLAIM 10 (Reference numerals added)	PRIOR ART
A device 78 for maintaining a patient fluid line access valve A having an access portion A10 with an end face that includes a septum A6 and external threads A4 on the	Figure 7 of White discloses an outer protective cap 78 for maintaining an access valve coupler 70, 82 for an indwelling catheter. The access valve 70, 82 has an end face that includes a septum 84 and external threads 74.

<p>access portion A10 proximate the septum A6, the device comprising:</p>	<p>To the extent White does not disclose external threads 74 near the septum 84 that is a matter of mere design choice.</p> <p>One of ordinary skill would relocate the internal threads 76 of White's cap 78 to correspond with the external threads 14 of the access valve of the Harding publication. Thus, the access valve of the preamble of claim 10 is met by the combination of White and Harding.</p>
<p>a housing 78 for covering the access portion A10 of the patient fluid line access valve A, the housing having an open end, a closed end, and a cavity, the housing including a thread 18 on an inner wall of the cavity for engaging the external threads A4 on the access portion A10 of the patient fluid line access valve A;</p>	<p>Referring to Fig. 7 of White, the outer protective cap 78 includes a housing for covering the proximal member or injection cap 82 of the coupler 70, 82, the housing having an open end, a closed end, and a cavity, the housing including internal threads 76 on an inner wall of the cavity for engaging the external thread 74 on the distal member 70 of the coupler.</p>
<p>a wet pad 80 impregnated with a cleaning solution prior to attachment of the housing 78 to the access portion A10 of the patient fluid line access valve A, the wet pad 80 being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads A4 of the access portion A10 of the patient fluid line access valve A when the housing is positioned over</p>	<p>Referring to Fig. 7 of White, a sponge 80 saturated with an antiseptic is positioned within the cavity of cap 78 for contacting the septum 84 to disinfect the septum 84.</p> <p>Although White does not expressly disclose that its solution disinfects at least a portion of the external threads, column 3, lines 39-45, and col. 2, lines 59-61, disclose that the antiseptic also flows along the walls of the proximal member 82. Also, col. 6, lines 58-66 teach that when the sponge 68 contacts septum 54, antiseptic material is <i>forced</i> within a space between proximal member</p>

<p>and covers the access portion A10; and</p>	<p>32 and outer protective cap 64 so that the connection between female member 20 and proximal member 32 is bathed with antiseptic." If the contact with the sponge forces antiseptic material within the noted space to reach apertures 50, it will certainly also reach at least a portion of the external threads 74. Also, White appreciates that threaded portions susceptible to pathogens. (See col. 2, lines 1-4, and col. 6, lines 58-66).</p> <p>In any event, Genatempo discloses with reference to Fig. 3, a protective cap 10 for a catheter that includes absorbent material 24 that retains an antiseptic or antibacterial agent. When the cap is placed on a catheter tube "an antibacterial effect is provided to main tubular member 40 of connector 32, <i>as well as threads 42 through migration of the antiseptic.</i>" Col. 3, lines 40-45 (emphasis added). One skilled in the art concerned with maintaining the access valve in an aseptic condition would appreciate the benefit of providing an antibacterial effect on the threads, and would be motivated to do so.</p>
<p>a lid 78a over the open end of the housing to seal the cavity with the wet pad 80 within the cavity and provide a moisture barrier, the lid 78a being removable to expose the wet pad 80 and allow insertion of the access portion A10 of the patient fluid line access valve A into the cavity so that the end face of the access portion A10 contacts the wet pad 80.</p>	<p>As noted above, the sponge 80 of White contacts the septum 84. The claim defines the end face to include the septum. Thus, sponge 80 contacting the septum 84 meets the limitation of the wet pad contacting the end face.</p> <p>Although White does not expressly disclose a lid, col. 3, lines 51-55 disclose that after removal of the outer protective cap 78, preferably a fresh, new outer protective cap 78 is then placed on the coupler. The new</p>

	<p>cap 78 apparently includes a lid or is placed in a package in order to protect the solution in sponge 80.</p> <p>In any event, Genatempo discloses in Fig. 1 a protective cap 10 having a <u>peelable lid 20</u>, as well as the cap 10 having an open end, a closed end, a cavity, an absorbent material 24 within the cavity and which retains volatile antibacterial agent, such as povidon iodine, and internal threads.</p> <p>One skilled in the art would readily appreciate combining the peelable lid 20 of Genatempo with White.</p>
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CLAIM 11 (Reference numerals added)	PRIOR ART
<p>The device of claim 10, wherein the cavity comprises an inner circumference 82 and the thread 18 comprises a length that is less than the inner circumference 82.</p>	<p>White shows that the cavity comprises an inner circumference and that the thread 76 comprises a length.</p> <p>Although it is not apparent whether the length of the “internal threads 76” of White is less than the inner circumference, this is a mere design choice dictated largely by the type of coupler or valve to which the device is to be attached. In fact, White would certainly be adapted with a thread comprising a length that is less than the inner circumference if being adapted to the access connector of Harding. Harding discloses a thread 14 which appears to be less than the circumference. Further, as</p>

	indicated by the examiner, Paradis teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).
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CLAIM 12	PRIOR ART
The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.	White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55). One of ordinary skill in the art would recognize that a povidone-iodine solution is as an antimicrobial agent. In fact, the '846 patent identifies povidone iodine as an example of an antimicrobial agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

CLAIM 13	PRIOR ART
The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	<p>White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55).</p> <p>Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an</p>

	<p>antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.</p> <p>Chlorhexidine diacetate is an obvious substitute. In fact, in paragraph [0030] of the published application, Hoang discloses that “Any of a number of antimicrobial agents may be used in wet pad 22. Some examples include chlorhexiden gluconate, chlorhexidine diacetate, chloroxylonol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc.” Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).</p>
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CLAIM 14	PRIOR ART
The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.	<p>White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55).</p> <p>Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.</p> <p>While White’s povidone iodine solution is not alcohol-based, it</p>

	would have been obvious to one of ordinary skill in the art to substitute an alcohol-based solution for povidone iodine in view of Busch's disclosure of isopropyl alcohol as an antiseptic solution. In addition, one skilled in the art would know that it was standard nursing practice, prior to the advent of protective caps, to wipe the access port septum with an alcohol wipe prior to accessing the septum.
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J. Claim 10 Is Obvious in View of Menyhay and Genatempo

Several substantial limitations of claim 10 of the '864 patent are disclosed by the Menyhay patent. Both Menyhay and claim 10 describe a disinfecting cap for an indwelling catheter access valve. (Menyhay, Ex. 1029, Abstract). As seen in Fig. 2 and the related text, each cap or cover 10 includes an open end, closed end and a cavity. A sponge 12 is located in the cover. The internal wall of the cover includes internal threads 15 for mating with the external threads 17 of an access valve or external injector port 19. The injector port 19 also includes an end face having a septum 18, wherein the threads 17 are proximate the septum 18. The cover also provides an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol. Col. 6, lines 47-49. Upon positioning the caps of Menyhay and claim 10 on an access valve, the sponges in both caps come

into contact with a septum and disperse aseptic solutions that bathe the septum and the surrounding structure of the access valve to prevent bacterial contamination. (Ex. 1029, sentence spanning columns 6 and 7). See also the O-ring 14 intended to seal the end of the cover 10. Col. 6, lines 59-61.

Menyhay and claim 10 differ in only three minor respects: Namely, the sponge 12 of Menyhay is not preloaded with the solution, whether the aseptic solution of Menyhay disinfects a portion of the external threads; and the absence of an express teaching of a peel-able lid on Menyhay's protective cap. The solution to these differences would have been readily obvious to a person of ordinary skill, given his or her's presumed knowledge of the teachings of the prior art Genatempo patent, as well as the inherent properties of the Menyhay cap.

First, the sponge 12 of Menyhay is not preloaded with the solution. Rather, Menyhay provides a breakable capsule 11 containing the solution. The capsule is ruptured when it is pressed firmly against projection 13 (Ex. 1029, col. 6, lines 49-51), thereby releasing the antiseptic agents inside to be soaked up by sponge 12 (Ex. 1029, col. 6, lines 63-64). However, Genatempo discloses that the absorbent material 24 is impregnated with a cleaning solution prior to attachment of the cap 10. See first paragraph of col. 3 and the Abstract (Ex. 1024). When the cover is removed, the patient is isolated from any potential hazard of the ruptured breakable capsule 11 only by the sponge 12. One skilled in the art would motivated to

consider the use of a preloaded absorbent material 24 over the use of a breakable capsule 11.

Second, Menyhay does not explicitly disclose that the aseptic solution in the sponge of the cap will contact "at least a portion of the external threads of the access portion" of the access valve, as specified by claim 10. This gap is amply filled by the Genatempo patent's express disclosure of a disinfecting cap similar to Menyhay that, when placed on a connector, provides "an antibacterial effect" to the connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, Col. 3, lines 43-45. One skilled in the art concerned with maintaining the access valve in an aseptic condition would readily be motivated to ensure that the arrangement of Menyhay would similarly provide such antibacterial effect to the external threads 74 of Menyhay.

Moreover, the person of ordinary skill would understand that the aseptic solution would also flow onto at least a portion of the external threads of the access valve given Menyhay's disclosures that an O-ring 14 is provided at or near the open end of the cylinder 10. (Ex. 1029, col. 6, lines 42-43), and that "When the present invention is screwed into place over the injection port, O-ring 14 creates a seal over the end of the port 19 (see Fig. 3). (Ex. 1029, col. 6, lines 59-61). It is readily apparent that the O-ring 14 is intended to retain the solution within the

cover. In fact, col. 7, lines 64-66 indicate that the “circumference of the inside of the cover should be slightly larger than the circumference of the stem of the port.”

It is also worth noting that the Patent Owner did not introduce a limitation requiring the disinfecting solution to contact the external threads of the access valve to the independent claims of the '864 application until January 2013. There is *no* disclosure in the written description of the '864 patent to support that limitation. Thus, a serious question exists as to whether this limitation would run afoul of the written description requirement of Section 112, unless it is inherent in the interface of the sponge of the disinfecting cap and the access valve septum that the disinfecting solution will reach the external threads. If that result is inherent in claim 10 of the '864 patent, it must also be inherent when the cap of Menyhay is placed on an access valve septum.

Third, Menyhay does not explicitly disclose a removable lid over the end of the disinfecting cap that engages the access valve to protect the aseptic solution prior to placing the cap on an access valve, as required by claim 10.³ But the use of a lid to preserve the solution, when using the preloaded sponge 24 of Genatempo, would have been obvious to one of ordinary skill in view of the Genatempo patent's disclosure of just such a lid for that purpose.

³ Menyhay does, however, disclose at Ex. 1029, col. 7, line 14-15 that a new sterile cover is contained in a sterile envelope.

Hence, claim 10 is obvious in view of Menyhay and Genatempo.

K. Claim 11 Is Obvious in Light of Menyhay and Paradis

Both Menyhay and claim 11 of the '846 patent disclose a cavity having an inner circumference and a thread having a length. It is not clear whether the length of the internal thread of Menyhay is less than the inner circumference. However, this is a trivial difference because a person of ordinary skill in the art would understand that this is a mere design choice dependent on the type of valve to which the cap is attached. It would be obvious for one of ordinary skill in the art to modify the cap in Menyhay to have a thread length less than an inner circumference. Further, as noted by the Examiner when rejecting the related claim 80, (Ex. 1017, p. 17, par. 43) the Paradis patent teaches a valve with threading of a length that is less than the circumference of cylindrical connector. See partial luer threads 43 in Fig. 4a. (Ex. 1025, p. 5).

L. Claim 12 Is Obvious in Light of Menyhay and Genatempo

Claim 12 of the '846 patent calls for the cleaning solution of claim 10 to be an "antimicrobial agent." Menyhay discloses a bactericidal (Ex. 1029, col. 6, line 49). Menyhay also discloses an antiseptic such as a povidone-iodine solution to keep the septum free of pathogens. One of ordinary skill in the art would recognize that a povidone-iodine solution is as an antimicrobial agent. In fact, the

'846 patent identifies povidone iodine as an example of an antimicrobial agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

M. Claim 13 Is Obvious in light of Menyhay, Genatempo and Busch

Claim 13 of the '846 requires an antimicrobial agent comprised of at least one of chlorhexidine gluconate or chlorhexidine diacetate. Menyhay does not specifically disclose the use of chlorhexidine gluconate or chlorhexidine diacetate. However, it would have been obvious to one of ordinary skill to substitute a chlorhexidine gluconate for Menyhay's use of a povidone-iodine solution in view of the Busch publication's disclosure of a skin preparation package including chlorhexidine gluconate as an antiseptic solution. Moreover, one having ordinary skill in the art would have seen chlorhexidine diacetate as an obvious substitute for povidone iodine because the '846 patent discloses that "[a]ny number of microbial agents may be used" including "chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chlorizde, octenidine, antibiotic, etc." Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).

N. Claim 14 Is Obvious in Light of Menyhay and Genatempo

Claim 14 of the '846 patent requires an alcohol-based cleaning solution. Menyhay discloses isopropyl alcohol (Ex. 1029, col. 6, line 48).

O. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of the comments above in paragraphs J – N.

CLAIM 10	
Menyhay, Harding, and Genatempo	
CLAIM 10 (Reference numerals added)	PRIOR ART
A device 78 for maintaining a patient fluid line access valve A having an access portion A10 with an end face that includes a septum A6 and external threads A4 on the access portion A10 proximate the septum A6, the device comprising:	Figs. 2, 3 and 6 of Menyhay show a cover 10 for maintaining an external injector port 19 for an indwelling catheter. The injector port 19 includes an access portion with an end face having a septum 18 and external threads 17 on the access portion proximate the septum 18.
a housing 78 for covering the access portion A10 of the patient fluid line access valve A, the housing having an open end, a closed end, and a cavity, the housing including a thread 18 on an inner wall of the cavity for engaging the external threads A4 on the access portion A10 of the patient fluid line access valve A;	Referring to Fig. 2 of Menyhay, the cover includes a housing 10 for covering the access portion, the housing having an open end, a closed end, and a cavity, the housing including internal threads 15 on an inner wall of the cavity for engaging the external thread 17 on the access portion of the injector port 19.

a wet pad 80 impregnated with a cleaning solution prior to attachment of the housing 78 to the access portion A10 of the patient fluid line access valve A, the wet pad 80 being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads A4 of the access portion A10 of the patient fluid line access valve A when the housing is positioned over and covers the access portion A10; and

Referring to Fig. 3 of Menyhay, a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol, the sponge 12 positioned within the cavity for contacting the end face 18 to disinfect the end face.

Menyhay does not disclose that the sponge 12 is impregnated prior to attachment of the housing 10 to the access portion. However, Genatempo discloses that the absorbent material 24 is impregnated with a cleaning solution prior to attachment of the cap 10. See first paragraph of col. 3 and the Abstract. One skilled in the art noting the potential hazard of the ruptured breakable capsule being exposed to the patient, would be motivated to consider the use of a preloaded absorbent material 24 over the use of a breakable capsule 11.

Although Menyhay does not expressly disclose that its solution disinfects at least a portion of the external threads, there are several references in Menyhay which strongly indicate that the external threads 17 are being disinfected. Col. 6, lines 60-61 disclose with reference to Fig. 3 that the O-ring 14 creates a seal over the end of the port 19. Fig. 3 makes it readily apparent that the seal is intended to retain the solution from the sponge 12 from moving past the o-ring 14. However, clearly the solution will first pass the external threads 17. In fact, col. 7, lines 64-66 indicate that the "circumference of the inside of the cover should be slightly larger than the circumference of the stem of the port." The sentence spanning columns 5 and 6 indicate

	<p>that the cover provides a “continuous aseptic immersion (bathing) of the injection port.” Col. 7 lines 4-6 indicate that the cover aseptically cleanse the “surface of an injection port.”</p> <p>In any event, Genatempo discloses with reference to Fig. 3, a protective cap 10 for a catheter that includes absorbent material 24 that retains an antiseptic or antibacterial agent. When the cap is placed on a catheter tube "an antibacterial effect is provided to main tubular member 40 of connector 32, <i>as well as threads 42 through migration of the antiseptic.</i>" Col. 3, lines 40-45 (emphasis added). One skilled in the art concerned with maintaining the access valve in an aseptic condition would appreciate the benefit of providing an antibacterial effect on the threads, and would be motivated to do so.</p>
<p>a lid 78a over the open end of the housing to seal the cavity with the wet pad 80 within the cavity and provide a moisture barrier, the lid 78a being removable to expose the wet pad 80 and allow insertion of the access portion A10 of the patient fluid line access valve A into the cavity so that the end face of the access portion A10 contacts the wet pad 80.</p>	<p>Menyhay does not disclose a lid.</p> <p>However, Genatempo shows in Fig. 1, in conjunction with a preloaded absorbent material 24, a protective cap 10 having a <u>peelable lid 20</u>, as well as the cap 10 having an open end, a closed end, a cavity, the absorbent material 24 within the cavity and which retains volatile antibacterial agent, such as povidon iodine, and internal threads.</p> <p>One skilled in the art would readily appreciate combining the peelable lid 20 of Genatempo with Menyhay, especially where the preloaded absorbent material 24 of Genatempo is incorporated for the reasons indicated above.</p>

CLAIM 11 (Reference numerals added)	PRIOR ART
<p>The device of claim 10, wherein the cavity comprises an inner circumference 82 and the thread 18 comprises a length that is less than the inner circumference 82.</p>	<p>Menyhay shows that the cavity comprises an inner circumference and that the thread 15 comprises a length.</p> <p>Although the length of the “internal threads 15” of Menyhay is not less than the inner circumference, this is a mere design choice dictated largely by the type of coupler or valve to which the device is to be attached. In fact, Menyhay would certainly be adapted with a thread comprising a length that is less than the inner circumference if being adapted to an access connector of a thread less than the inner circumference. For example, as indicated by the examiner (Ex. 1017, p. 17, par. 43), Paradis teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).</p>

CLAIM 12	PRIOR ART
<p>The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.</p>	<p>Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.</p>

CLAIM 13	PRIOR ART
<p>The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.</p>	<p>Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.</p> <p>Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.</p> <p>Chlorhexidine diacetate is an obvious substitute. In fact, in paragraph [0030] of the published application, Hoang discloses that "Any of a number of antimicrobial agents may be used in wet pad 22. Some examples include chlorhexiden gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc." Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).</p>

CLAIM 14	PRIOR ART


The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.	Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.
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IX. CONCLUSION

For the reasons described above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 10-14 (application claims 79-83) of the '864 Patent. Accordingly, *inter partes* review of claims 10-14 of the '864 Patent is respectfully requested.

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(Trial No. _____)

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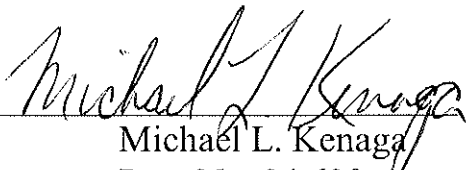
Petition for *Inter Partes* Review of U.S. Patent No. 8,740,864

CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)

Pursuant to 37 C.F.R. §§ 42.8(e) and 42.105(b), the undersigned certifies that on the 3rd day of June 2014, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via Courier, postage prepaid, to the Patent Owner by serving the correspondence address of record for the '864 Patent:

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

Respectfully Submitted,
IpHorgan Ltd.

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(Trial No. _____)

ATTORNEYS FOR PETITIONER

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

Patent No. 8,740,864

Issued Date: June 3, 2014

Title: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL
CAP/CLEANER

Trial No. Unassigned


PETITIONER'S POWER OF ATTORNEY
IN AN *INTER PARTES* REVIEW
37 C.F.R §42.10(b)

Petitioner, Excelsior Medical Corporation, hereby appoints the following practitioners as its attorneys to represent Petitioner before the United States Patent and Trademark Office (USPTO) in connection with the above-captioned inter partes review of U.S. Patent No. 8,740,864:

Lead Counsel for Petitioner	Back-Up Counsel for Petitioner
Michael L. Kenaga Reg. No. 34639 IpHorgan Ltd. 195 Arlington Heights Road Suite 125 Buffalo Grove, Illinois 60089 (PH) 847-808-5500 (FX) 847-808-7238 patentmail@iphorgan.net	Sean S. Swidler Reg. No. 49033 IpHorgan Ltd. 195 Arlington Heights Road Suite 125 Buffalo Grove, Illinois 60089 (PH) 847-808-5500 (FX) 847-808-7238 patentmail@iphorgan.net

The individual whose signature and title is supplied below is authorized to act on behalf of the Petitioner, Excelsior Medical Corporation.

For: Petitioner, Excelsior Medical Corporation

By: 

Christopher E. Gardner
Printed or typed name

Vice President of Product Development
Title

May 30, 2014
Date

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

Patent No. 8,740,864

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The individual whose signature and title is supplied below is authorized to act on behalf of the Petitioner, Excelsior Medical Corporation.

For: Petitioner, Excelsior Medical Corporation

By: 

Christopher E. Gardner
Printed or typed name

Vice President of Product Development
Title

May 30, 2014
Date

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 IPR2014-00800
Patent 8,740,864

Mailed: June 16, 2014

Before Andrew Kellogg, *Trial Paralegal*

NOTICE OF FILING DATE ACCORDED TO PETITION
AND
TIME FOR FILING PATENT OWNER PRELIMINARY RESPONSE

The petition for *inter partes* review in the above proceeding has been accorded the filing date of June 3, 2014.

Administrative Patent Judge Mitchell G. Weatherly has been designated to manage the proceeding. 37 C.F.R. § 42.5.

A review of the petition identified the following defect(s):

Improper usages of claim charts: Although claim charts are permitted, the purpose of claim charts is to assist petitioners to specify where each claim limitation is found in the prior art references relied upon. Claim charts should be free from attorney argument.

Claim Construction: Petitions must identify “[h]ow the challenged claim is to be construed.” 37 C.F.R. § 42.104(b)(3). In most cases, claim construction is an important step in the determination of whether the challenged claims are unpatentable over the cited prior art. In the instant petition no individual claim terms are given specific construction.

Petitioner must correct the defect(s) within **FIVE BUSINESS DAYS** from this notice. Failure to correct the defect(s) may result in an order to show cause as to why the Board should institute the trial. No substantive changes (e.g., new grounds) may be made to the petition.

Patent Owner may file a preliminary response to the petition no later than three months from the date of this notice. The preliminary response is limited to setting forth the reasons why the requested review should not be instituted. Patent Owner may also file an election to waive the preliminary response to expedite the proceeding. For more information, please consult the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 (Aug. 14, 2012), which is available on the Board Web site at <http://www.uspto.gov/PTAB>.

Patent Owner is advised of the requirement to submit mandatory notice information under 37 C.F.R. § 42.8(a)(2) within 21 days of service of the petition.

The parties are encouraged to use the heading on the first page of this Notice for all future filings in the proceeding.

The parties are advised that under 37 C.F.R. § 42.10(c), recognition of counsel *pro hac vice* requires a showing of good cause. The parties are authorized to file motions for *pro hac vice* admission under 37 C.F.R. § 42.10(c). Such motions shall be filed in accordance with the “Order -- Authorizing Motion *for Pro Hac Vice* Admission” in Case IPR2013-00639, Paper 7, a copy of which is available on the Board Web site under “Representative Orders, Decisions, and Notices.”

The parties are reminded that unless otherwise permitted by 37 C.F.R. § 42.6(b)(2), all filings in this proceeding must be made electronically in the Patent Review Processing System (PRPS), accessible from the Board Web site at <http://www.uspto.gov/PTAB>.

If there are any questions pertaining to this notice, please contact Andrew Kellogg at 571-272-5366 or the Patent Trial and Appeal Board at 571-272-7822.

Case IPR2014-00800
Patent 8,740,864

For PETITIONER:

Michael Kenaga
Sean Swidler
IpHorgan Ltd.
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For PATENT OWNER:

David W. Highet, VP & Chief IP Counsel
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Franklin Lakes NJ 07417-1880

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

Mailed: June 18, 2014

Before Andrew Kellogg, *Trial Paralegal*

CORRECTED NOTICE OF FILING DATE ACCORDED TO PETITION
AND
TIME FOR FILING PATENT OWNER PRELIMINARY RESPONSE

The petition for *inter partes* review in the above proceeding has been accorded the filing date of June 3, 2014.

Administrative Patent Judge Mitchell G. Weatherly has been designated to manage the proceeding. 37 C.F.R. § 42.5.

A review of the petition identified the following defect(s):

Improper usages of claim charts: Although claim charts are permitted, the purpose of claim charts is to assist petitioners to specify where each claim limitation is found in the prior art references relied upon. Claim charts should be free from attorney argument.

Claim Construction: Petitions must identify “[h]ow the challenged claim is to be construed.” 37 C.F.R. § 42.104(b)(3). In most cases, claim construction is an important step in the determination of whether the challenged claims are unpatentable over the cited prior art. In the instant petition no individual claim terms are given specific construction.

Petitioner must correct the defect(s) within **FIVE BUSINESS DAYS** from this notice. Failure to correct the defect(s) may result in an order to show cause as to why the Board should institute the trial. No substantive changes (e.g., new grounds) may be made to the petition.

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The parties are reminded that unless otherwise permitted by 37 C.F.R. § 42.6(b)(2), all filings in this proceeding must be made electronically in the Patent Review Processing System (PRPS), accessible from the Board Web site at <http://www.uspto.gov/PTAB>.

If there are any questions pertaining to this notice, please contact Andrew Kellogg at 571-272-5366 or the Patent Trial and Appeal Board at 571-272-7822.

Case IPR2014-00880
Patent 8,740,864

For PETITIONER:

Michael Kenaga
Sean Swidler
IpHorgan Ltd.
patentmail@iphorgan.net

For PATENT OWNER:

David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
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Franklin Lakes NJ 07417-1880

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

CORRECTED PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.*

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

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List of Exhibits

Petitioner Exhibit No.	Exhibit
Ex. 1001	Issue Notification for U.S. Patent No. 8,740,864
Ex. 1002	U.S. Patent Publication 2007/0112333 to Hoang for “Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner”
Ex. 1003	U.S. Divisional Patent No. 8,491,546 to Hoang for “Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner”
Ex. 1004	Requirement for Restriction/Election mailed July 29, 2009
Ex. 1005	Restriction Response filed August 24, 2009
Ex. 1006	Non-Final (First) office action mailed November 25, 2009
Ex. 1007	“Amendment A” filed February 19, 2010
Ex. 1008	Final (Second) office action mailed June 11, 2010
Ex. 1009	“Amendment B” filed November 12, 2010
Ex. 1010	Non-final (Third) office action mailed April 10, 2012
Ex. 1011	Applicant Initiated Interview Summary May 30, 2012
Ex. 1012	“Amendment C” filed June 28, 2012
Ex. 1013	Final (Fourth) office action mailed September 25, 2012
Ex. 1014	Applicant Initiated Interview Summary January 23, 2013
Ex. 1015	“Amendment D” filed January 24, 2013
Ex. 1016	Applicant Initiated Interview Summary August 15, 2013
Ex. 1017	Non-final (Fifth) office action mailed August 15, 2013
Ex. 1018	“Amendment E” filed November 14, 2013
Ex. 1019	Examiner Initiated Interview Summary January 21, 2014
Ex. 1020	Applicant Initiated Interview Summary April 7, 2014
Ex. 1021	WHITE, U.S. Patent No. 5,242,425
Ex. 1022	HARDING 2003, U.S. Patent Publication No. 2003/009853
Ex. 1023	HARDING 2008, U.S. Patent Publication No. 2008/0027399
Ex. 1024	GENATEMPO, U.S. Patent No. 4,440,207
Ex. 1025	PARADIS, U.S. Patent No. 6,117,114
Ex. 1026	BUSCH, U.S. Patent Publication No. 2004/0004019
Ex. 1027	LAKE, U.S. Patent Publication No. 2004/0258560
Ex. 1028	PELUSO, U.S. Patent No. 4,624,664
Ex. 1029	MENYHAY, U.S. Patent No. 5,554,135
Ex. 1030	LYNN, U.S. Patent Publication No. 2002/0193752

Ex. 1031	35 U.S.C. 103(a) as effective prior to March 16, 2013
Ex. 1032	<i>KSR Int'l v. Teleflex Inc.</i> , 550 U.S. 398 (2007)
Ex. 1033	<i>Philips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)
Ex. 1034	<i>Graham v. John Deere</i> , 381 U.S. 1 (1966)
Ex. 1035	<i>In re Bigio</i> , 381 F.3d 1320 (Fed. Cir. 2004)
Ex. 1036	<i>Okajima v. Bourdeau</i> , 261 f.3d 1350 (Fed. Cir. 2001)
Ex. 1037	Declaration of Terry Layton, Ph.D.

I. INTRODUCTION

Petitioner seeks *inter partes* review of claims 10 to 14 of U.S. Patent No. 8,740,864 (the "'864 patent"), which issued on June 3, 2014, to Becton, Dickinson and Company ("Patent Owner"). Petitioner relies on new prior art -- U.S. Publication No. 2003/0109853 to Harding, et al. (Ex. 1022) -- that was not before the examiner during the prosecution of the '864 patent. In addition, Petitioner shows that the examiner did not fully appreciate the disclosures of the primary references during prosecution, including U.S. Patent No. 5,242,425 to White (Ex. 1021), and U.S. Patent No. 4,440,207 to Genatempo (Ex. 1024).

II. MANDATORY NOTICES

A. Real Party-In-Interest

Petitioner Excelsior Medical Corporation is the real party-in-interest.

B. Related Matters

Petitioner is filing, concurrent with this petition, a declaratory judgment action in the District of New Jersey against Patent Owner and its exclusive licensee, Ivera Medical Corporation, entitled *Excelsior Medical Corporation v. Becton, Dickinson and Company, et al*, 14-cv-03502. Patent Owner and its exclusive licensee, Ivera Medical Corporation, are filing, concurrent with this petition, an action for patent infringement in the Southern District of California, entitled *Ivera Medical Corporation and Becton, Dickinson and Company v.*

Excelsior Medical Corporation, Covidien LP, and Covidien Sales, LLC, 14-cv-1348.¹ There are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

C. Lead and Back-Up Counsel

Petitioner is represented by Michael L. Kenaga (Reg. No. 34,639) as lead counsel, and Sean S. Swidler (Reg. No. 49,033) as back-up counsel. The addresses for both are:

IpHorgan Ltd.
195 Arlington Heights Road
Suite 125
Buffalo Grove, IL 60089-1768
(PH) 847-808-5500
patentmail@iphorgan.net

D. Power of Attorney

Petitioner submits herewith a power of attorney in favor of the lead and back-up counsel identified above.

E. Service Information

The service information for Petitioner required under §42.8(b)(4)(i-v) is set out above under the designation of lead and back-up counsel. Electronic service is approved and preferred.

¹ The related matters notice is updated herein within 21 days of a change of the related matters notice per §42.8(a)(3).

III. PETITION FEE

The undersigned authorizes the Office to charge \$23,000.00 to Deposit Account No. 50-3993 in payment of the fee required under §42.15(a)(1) for filing a request for *inter partes* review, and under §42.15(a)(2) for *inter partes* review post-institution. Petitioner submits that the fees required by §42.15(a)(3) and §42.15(a)(4) are not applicable because this Petition seeks review of only five claims.

IV. GROUNDS FOR STANDING

As required under §42.104(a), Petitioner certifies that the '864 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting such review on the grounds identified in this Petition.

V. RELIEF REQUESTED

A. Statement of Precise Relief Requested

As required by §42.22(a)(1) and §42.104(b), Petitioner asks the Board to initiate *inter partes* review on challenged claims 10 to 14 of the '864 patent on all grounds of unpatentability asserted against each claim, and to cancel claims 10 to 14.

B. Full Statement of Reasons for the Relief Requested

Petitioner provides a full statement of the reasons for the relief requested, including a detailed explanation of the significance of the material facts and governing law, below.

VI. CLAIMS CHALLENGED ON THE BASIS OF SPECIFIC PRIOR ART

As required by §42.22(a)(1-2) and §42.104(b)(1-2), Petitioner challenges the claims in issue as obvious under 35 U.S.C. 103(a) (pre-AIA) on the basis of the following prior art combinations:

- A. Claim 10 -- White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- B. Claim 11 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- C. Claim 12 -- White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- D. Claim 13 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- E. Claim 14 -- White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- F. Claim 10 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).

- G. Claim 11 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- H. Claim 12 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).
- I. Claim 13 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Busch (Ex. 1026).
- J. Claim 14 -- Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).

VII. THE '864 PATENT

A. Overview of the '864 Patent

The '864 patent issued on June 3, 2014, from an application, serial no. 11/281,711, filed on November 17, 2005.

The '864 patent is directed to an antimicrobial cap for a patient fluid line (catheter) access valve that is left in a patient's body during an extended treatment regimen. The access valve contains a septum into which a male luer (or needle) is inserted to administer medicine or other liquids to a patient through a catheter. The disinfecting cap is placed over the access valve when the patient is not being treated to prevent bacterial contamination of the access valve that could cause infections and other maladies. (See Abstract, and the sixth paragraph of the Detailed Description).

Claims 10 to 14 provide:

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:

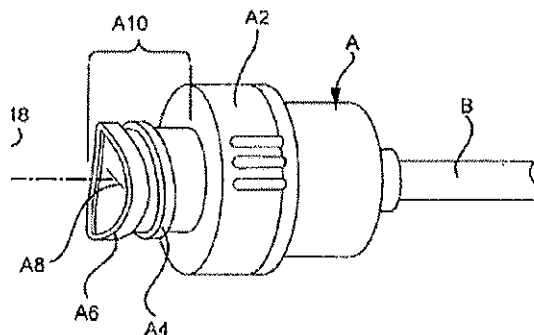
a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve;

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.

11. The device of claim 10, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.
12. The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.
13. The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.
14. The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.

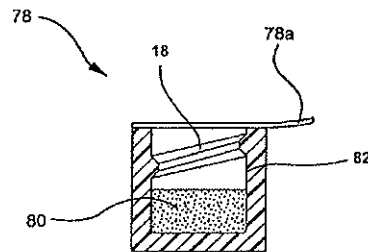
Hence, the preamble of claim 10 calls for a protective cap for an "access portion" of an access valve with "an end face that includes a septum and external threads . . . proximate the septum." The access portion, septum, and threads of the access valve of claim 10 are illustrated below in the partial reproduction of Figure 1 (and described in the associated text) of the '864 patent as items A6 (septum), A4 (thread), and A10 (access portion).



7. The subsequent limitations of claim 10 require:

(i) a cap 78 with threads 18 on the inner wall of the cavity of the cap to engage the external threads [A4] of the access portion [A10] of the access valve [A];

FIG. 10B



(ii) a "wet pad [80] impregnated with a cleaning solution" in the cavity "for contacting the end face [of the septum A6 of fig. 1] ...and at least a portion of the external threads [A4] of the access portion" of the access valve; and

(iii) a removable lid 78A over the open end of the cap to protect the wet pad until the lid is removed and the cap is attached to access valve "so that the end face of the access portion contacts the wet pad."

8. Dependent claim 11 calls for the cavity of the cap to have an inner circumference 82 with a thread 18 that comprises a length that is less than the inner circumference. Dependent claim 12 specifies that the cleaning solution of claim 10 is an antimicrobial agent. Dependent claim 13, in turn, requires the

antimicrobial agent of claim 12 to be at least one of chlorhexidine gluconate and chlorhexidine diacetate. Lastly, dependent claim 14 calls for the cleaning solution of claim 10 to be an alcohol-based cleaning solution.

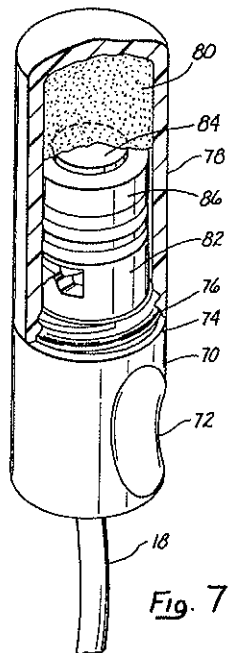
B. The Prior Art

1. The White Patent

United States Patent No. 5,242,425 to White, et al. (Ex. 1021, "White" or the "White patent") issued in 1993. White shows that the use of catheter access valves long pre-dates the 2005 filing of the Hoang patent application, and that it has been well known for almost as long that patients run a high risk of infection if an access valve is not properly maintained to prevent contamination by bacteria. (Ex. 1021, col. 2, lines 27-34). The White patent discloses an answer to the contamination/infection problem in the form of a cap, containing a sponge with a disinfecting solution, that is placed over a catheter access valve when it is not being used to treat a patient.

More specifically, as shown in Figure 7 and described in the associated text of the White patent, an outer protective cap 78 contains a sponge 80 saturated with an antiseptic. The cap 78 has internal threads 76 at the open, distal end. The protective cap fits on a catheter coupler (or access) assembly 70, 82 with a self-

sealing septum 84, injection cap 82, and external shoulder threads 74 to receive the internal threads 76 of the protective cap 78.

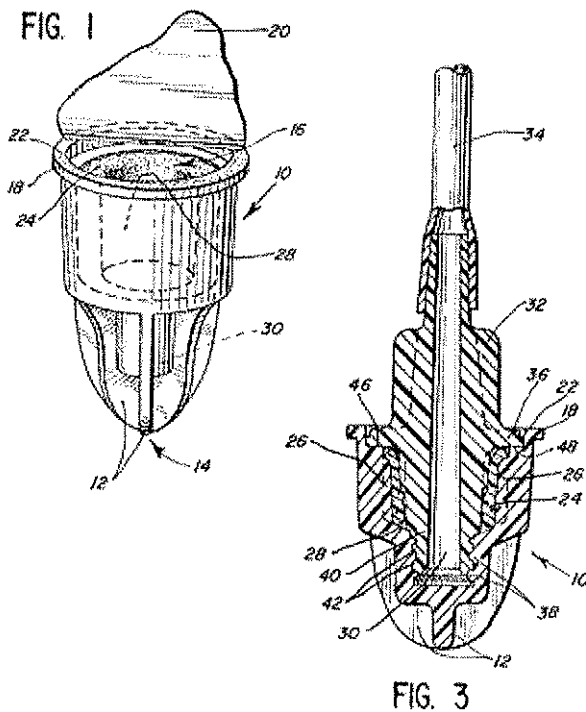


The protective cap 78 is spaced from the injection cap 82 "to permit antiseptic to bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84" when the cap is placed on the access valve assembly 70. (Ex. 1021, col. 7, lines 29-32).

White also discloses in another embodiment in Figs. 1-6 an outer protective cap 64 having a sponge 68 saturated with an antiseptic material. The cap 64 does not include threads but rather snap-fits onto a catheter coupler 10, 32 having a septum 54.

2. The Genatempo Patent

United States Patent No. 4,440,207 to Genatempo, et al. (Ex. 1024, "Genatempo" or the "Genatempo patent"), issued in 1984. As seen in Figs. 1 and 3 shown below, Genatempo also discloses a protective cap 10 containing absorbent material 24 saturated with antiseptic liquid that is placed in contact with a connector 32 attached to medical tubing 34, such as a catheter, to prevent contamination of the connector 32 before or between uses. (See Ex. 1024, col. 2, lines 66-68 and col. 3, lines 22, 23, 32-35, 40 and 41).



A removable, peel-back, lid 20 covers the open end of the cap 10 to prevent loss of the antiseptic liquid prior to use. In addition, the internal wall of the cap has threads 38 to engage the external threads 42 of a connector 32. As shown in Figure

3 and described in the specification of the Genatempo patent, when the cap is placed on a connector "an antibacterial effect" is provided to the connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, col. 3, lines 43-45).

3. The Harding Publication

U. S. Publication No. 2003/0109853 to Harding, et al. (Ex. 1022, "Harding" or the "Harding publication"), was published on June 12, 2003. The Patent Owner was the assignee of Harding at the time of filing and publication, but did not disclose the Harding publication or its subject matter to the examiner during prosecution of the '864 patent.

Harding discloses a catheter access valve that is remarkably similar, if not identical, to the access valve depicted in Figure 1 of the '864, as illustrated by, for example, the access valves of Figure 4 of Harding and part of Figure 1 of the '864 patent:

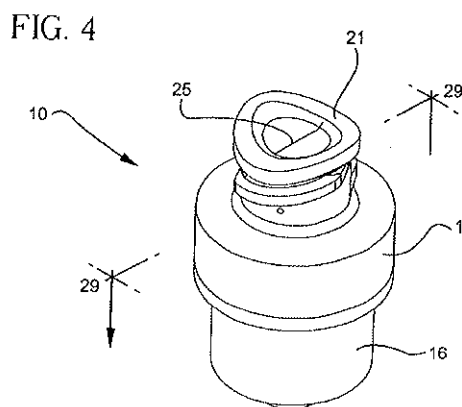
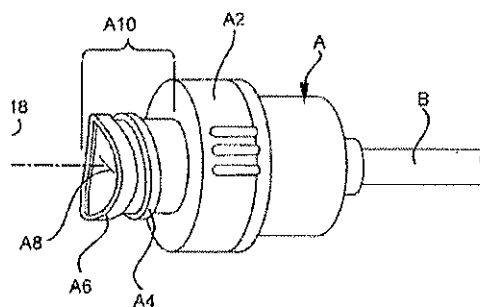


FIG. 4 of HARDING



PART OF FIG. 1 OF '864 PATENT

The Harding access valve 10 includes a top portion 12 that contains a septum 20 and has exterior luer threads 14 adjacent the septum "that allow another medical device having a male luer lock to be connected to the top of proximal portion 12." (Ex. 1022, paragraph [0073]).

4. The Paradis Patent

U. S. Patent No. 6,117,114 to Paradis (Ex. 1025, the "Paradis patent"), issued in 2000, teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).

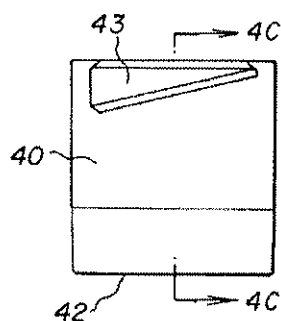


Fig. 4A

5. The Busch Patent

U. S. Publication No. 2004/0004019 to Busch, was published on January 8, 2004 (Ex. 1026, "Busch" or the "Busch publication"). It discloses "a presoaked preparation swab, sponge, applicator, or the like" that is saturated with antiseptic liquid and used to prevent contamination. The cleaning solution may be "[b]etadine or another antiseptic solution (e.g. alcohols, iodophors, chlorhexadine,

chlorhexadine gluconate with isopropyl alcohol, etc.).” (Ex. 1026, paragraph [0026]).

6. The Menyhay Patent

U.S. Patent No. 5,554,135 to Menyhay issued September 10, 1996. (Ex. 1029). It discloses in Fig. 2 (reproduced below) an external injector port 19, with an access portion having external threads 17, and an end face having a septum 18. A catheter 25 extends from the port 19. A cover 10 is shown having an open end and a closed end, forming a cavity (Fig. 2). An internal wall of the cover 10 includes internal threads 15. The closed end includes an inwardly pointed projection 13. The cover 10 receives the breakable capsule 11 and sponge 12. The breakable capsule 11 includes an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol. Ex. 1029, col. 6, lines 44-58.

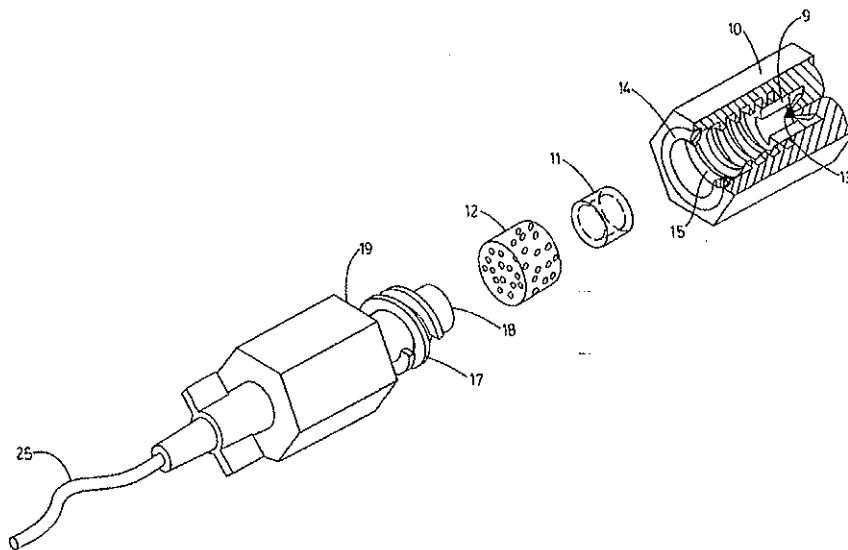


Fig. 2 of Menyhay

C. **Summary of Prosecution of the '864 Patent**

Although the application for the '864 was filed in 2005, the first office action did not occur until July 2009 when the examiner issued a restriction requirement because the original application claims covered a combination cleaner and cap 10 (see, e.g., Figures 1-4, 6-9) as well as the independent, standalone disinfecting cap 78 of Figure 10B. See Restriction mailed July 29, 2009 (Ex. 1004). The patent owner elected to proceed with the cap alone.²

The examiner issued five substantive rejections of claims proposed by the Patent Owner throughout prosecution of the '864 application in view of, among other references, White, Genatempo, Paradis, and Busch. Finally, in the fifth office action on the merits of August 15, 2013 (Ex. 1017), the examiner indicated that, upon curing an antecedent basis rejection, new dependent application claim 71 would be allowable because it provided that the internal threads of the cap "receive[] the external threads thereby causing the interface to advance into the inner cavity such that the septum contacts the wet pad."

² The Patent Owner filed a divisional application covering the combination cleaner and cap, which issued as U.S. Patent No. 8,491,546 on July 23, 2013 (Ex. 1003).

The examiner otherwise rejected application claim 79 (now issued claim 10) in the fifth office action as obvious because White disclosed all the features of claim 79 except for a lid, and that Genatempo disclosed the lid missing from White. Dependent application claims 80 to 83 were rejected in light of combinations of White, Genatempo, Paradis, and Busch.

In response to the fifth office action, the Patent Owner cancelled application claim 71 and amended independent application claims 69 and 84 (now, issued claims 1 and 15) to require rotation of the internal threads of the cap with the external threads of the access valve to cause the wet pad to come into contact with the septum.

However, the Patent Owner did not amend claim 79 to include such a rotational limitation. Instead, claim 79 was simply amended to require that the wet pad "disinfect[] the end face and a portion of the external threads" of the access valve.

With a minor, irrelevant change, the examiner allowed application claims 69, 70, and 72 to 88, as so amended, on January 21, 2014. In his reasons for allowance, the examiner cited the rotational limitations added to application claims 69 and 84:

The prior art does not disclose or render obvious the combination as claimed specifically including housing have 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.

See Examiner's Statement of Reasons for Allowance (Ex. 1019, pages 7 and 8).

Forgetting about White, the examiner wrongly determined that Genatempo was the closest prior art, finding that "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 [sic] the wet pad and is no longer in contact." That is a correct description of Genatempo as its Figure 3 shows that the end face near reference arrow 42 is located in cavity 30 below the wet pad 24.

In a subsequent interview initiated by the Patent Owner on April 1, 2014, the examiner acknowledged that application claim 79 does not require rotational movement of the cap and that it is enough that the housing wet pad engage the access portion. The examiner again noted Genatempo does not teach or suggest that the end face of a septum comes into contact with a pad as discussed above. See Applicant Initiated Interview Summary, (Ex. 1020, p.4). White was not discussed. (Ex. 1020, p. 2).

VIII. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Claim Construction

As required by §42.22(a)(2) and §42.104(b)(3), Petitioner submits that the claim terms of issued claims 10-14 are to be given their broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the disclosure.

The term “access portion” is described in the ‘864 patent as being formed by “[t]he exposed surface of septum A6 along with at least a portion of the exposed surface of housing A2 that surrounds septum A6” (Ex. 1002, p. 9, par. [0017]). Thus, a person of ordinary skill in the art would understand the broadest reasonable interpretation of “access portion” to encompass the portion of the access valve formed by the exposed surface of the septum and at least a portion of the exposed surface of the housing.

The ‘864 patent describes “cleaning solution” as “typically an alcohol- or water-based solution” where a “suitable alcohol-based solution contains about 50% to about 100% . . . of an alcohol solution” (Ex. 1002, p. 10, par. [0028]), “[s]uitable water-based solutions contain about . . . 90% to about 99% water” and “optional materials may also be added such as fragrance, dye, surfactant, emollient, etc.”

(Ex. 1002, p. 10, par. [0029]). Thus, a person having ordinary skill in the art would understand the broadest reasonable interpretation of the term “cleaning solution” is a solution used for cleaning.

The term “lid” is described in the ‘864 patent such that “[a]ny type of material or seal may be used as long as a moisture barrier is provided” (Ex. 1002, p. 9, par. [0019]). Thus, a person having ordinary skill in the art would understand the broadest reasonable interpretation of the term “lid” to encompass any material or seal that provides a moisture barrier.

The term “length” as used in claim 11 is not described in the ‘864 patent, and was only first introduced in claims 70, 80, and 85 in Amendment D (Ex. 1015, p. 2, 4, 5) and discussed in Amendment D (Ex. 1015, p. 7, 8), the Fifth Office Action (Ex. 1017, p. 3, 5), and Amendment E (Ex. 1018, p. 6, 7, 9-10). It should be construed in its broadest reasonable interpretation to mean the helical length of the thread along the walls of the inner cavity. In the alternative, “length” should be construed to mean the axial length of the threaded portion of the inner cavity.

B. Ordinary Skill in the Art

Petitioner submits that the relevant person of ordinary skill in the art includes one skilled in the art of patient fluid line access valve antimicrobial caps. Examples of such persons skilled in the art prior to the filing date of November 17, 2005 of the underlying application, may be inferred from the following prior art.

Patent Publication No.	Exhibit No.
WHITE, U.S. Patent No. 5,242, 425	Ex. 1021
HARDING 2003, U.S. Patent Publication No. 2003/009853	Ex. 1022
HARDING 2008, U.S. Patent Publication No. 2008/0027399	Ex. 1023
GENATEMPO, U.S. Patent No. 4,440,207	Ex. 1024
PARADIS, U.S. Patent No. 6,117,114	Ex. 1025
BUSCH, U.S. Patent Publication No. 2004/0004019	Ex. 1026
LAKE, U.S. Patent Publication No. 2004/0258560	Ex. 1027
PELUSO, U.S. Patent No. 4,624,664	Ex. 1028
MENYHAY, U.S. Patent No. 5,554,135	Ex. 1029

C. The Obviousness Framework

An invention that would have been obvious to a person having ordinary skill in the relevant art is not patentable. 35 U.S.C. §103(a) (pre-AIA). (Ex. 1031, p. 1)

As established in *Graham v. John Deere Co.*, 383 U.S. 1, ___ (1966), obviousness is a question of law that is resolved, in part relevant here, in light of following factual inquiries: (i) the scope and content of the prior art; (ii) the level of ordinary skill in the art; and (iii) the differences between the between the claimed invention and the prior art. Based on those factual inquiries, the focus in determining obviousness is on what a person of ordinary skill in the relevant art would have known at the time of the invention and on what that person would have been able to do with that knowledge. M.P.E.P. § 2141(II).

The scope and content of the prior art has been detailed above. The cited references are plainly relevant as they are from the same field of endeavor as the claimed inventions and are pertinent to the problem confronting the inventor. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). (Ex. 1035).

Petitioner submits that the level of skill of the hypothetical person of ordinary skill in the art may be inferred from the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). (Ex. 1036). Alternatively, petitioner's expert, Dr. Terry Layton, opines that a person of ordinary skill would have a bachelor's degree in biomechanical or mechanical engineering and a minimum of two to three years of work experience in the development and design of medical devices that connect to catheters or tubes where bacterial contamination may be an issue. Layton Dec., ¶ 20.

Petitioner discusses immediately below the differences between the prior art and the subject matter of claims 10 to 14, giving the claims "the broadest reasonable interpretation consistent with the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). (Ex. 1033).

D. Claim 10 Is Obvious in View of White, Harding, and Genatempo

Several substantial limitations of claim 10 of the '864 patent are disclosed by the White patent. Both White and claim 10 describe a disinfecting cap for an

indwelling catheter access valve. (Ex. 1021, col. 2, lines 53-61). Each cap contains a sponge that is saturated with an aseptic solution, and each cap has internal threads for mating with the external threads of a catheter access valve. (Ex. 1021, col. 7, lines 26-29). Upon positioning the caps of White and claim 10 on an access valve, the sponges in both caps come into contact with a septum and disperse aseptic solutions that bathe the septum and the surrounding structure of the access valve to prevent bacterial contamination. (Ex. 1021, col. 7, lines 29-32). Layton Dec. Ex. 1037, ¶ 22.

White and claim 10 differ in only three minor respects: namely, as to the location of the external threads of the access valve of White; whether the aseptic solution of White disinfects a portion of the external threads; and the absence of an express teaching of a peel-able lid on White's protective cap. The solution to these differences would have been readily obvious to a person of ordinary skill, given his or her's presumed knowledge of the teachings of the prior art Harding publication and Genatempo patent, as well as the inherent properties of the White cap.

First, White may not meet the limitation of the preamble of claim 10, requiring that the external threads of the access valve be "proximate" the septum, because the external threads 74 of the access valve of White are near the shoulder of the valve. (Ex. 1021, col. 7, lines 23-25).

However, one of ordinary skill in the art would have known that the Harding publication discloses an access valve with external threads near the septum that is very similar, if not identical, to the access valve of the '864 patent and claim 10. Layton Dec. Ex. 1037, ¶ 23. Hence, charged with the task of designing a disinfecting cap for an access valve with threads near the septum, it would have been an utterly predictable and simple matter for a person of ordinary skill to relocate the internal threads of the White cap away from the opening so that, when placed on access valve with external threads near a septum as disclosed in Harding, the sponge of the White cap would make contact with the septum to cause the disinfectant to bath the septum and surrounding area. Layton Dec. Ex. 1037, ¶ 23. Thus, modifying the protective cap 78 of White to adapt to the access connector of Harding would provide the identical arrangement as recited by the preamble of claim 10. KSR, 550 U.S. 398, 417 (2007) ("If a person of ordinary skill can implement a predictable variation, and would see the benefit of doing so, §103 likely bars [an invention's] patentability.")

Second, White does not explicitly disclose that the aseptic solution in the sponge of the cap will contact "at least a portion of the external threads of the access portion" of the access valve, as specified by claim 10. This gap is amply filled by the Genatempo patent's express disclosure of a disinfecting cap similar to White that, when placed on a connector, provides "an antibacterial effect" to the

connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, col. 3, lines 43-45). One skilled in the art would readily be motivated to ensure that the arrangement of White would similarly provide such antibacterial effect to the external threads 74 of White in modifying White to accommodate the access connector of Harding.

Moreover, the person of ordinary skill would understand that the aseptic solution would also flow onto at least a portion of the external threads of the access valve given White's disclosures that:

"the antiseptic material is *forced* within a space between proximal member 10 (sic, "32") and outer protective cap 64 (Ex. 1021, col. 6, lines 60-63),"

and that

"[t]he outer protective cap 78 [of Figure 7] is spaced from proximal member or injection cap 82 to permit antiseptic to bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84 (Ex. 1021, col. 7, lines 29-32.

Layton Dec. Ex. 1037, ¶ 25-28. Still further, adapting the cap 78 of White to engage the external threads near the septum of the access valve of Harding will result in the sponge 80 being closer to the external threads. Thus, increasing the

likelihood of the solution of White to disinfect at least a portion of the external threads.

It is also worth noting that the Patent Owner did not introduce a limitation requiring the disinfecting solution to contact the external threads of the access valve to the independent claims of the '864 application until January 2013. There is *no* disclosure in the written description of the '864 patent to support that limitation. Thus, a serious question exists as to whether this limitation would run afoul of the written description requirement of Section 112, unless it is inherent in the interface of the sponge of the disinfecting cap and the access valve septum that the disinfecting solution will reach the external threads. If that result is inherent in claim 10 of the '864 patent, it must also be inherent when the cap of White is placed on an access valve septum.

Third, White does not explicitly disclose a removable lid over the end of the disinfecting cap that engages the access valve to protect the aseptic solution prior to placing the cap on an access valve, as required by claim 10.³ But the use of a lid to preserve the solution in the White sponge would have been obvious to one of

³ White does, however, disclose at col. 3, lines 51-55, that after removal of the outer protective cap 78, a preferably fresh new outer protective cap 78 is placed on the coupler. The new cap 78 apparently includes a lid or is placed in a package in order to maintain a sterile nature prior to its use.

ordinary skill in view of the Genatempo patent's disclosure of just such a lid for that purpose. Indeed, it is inconceivable, as basic matters of hygiene and commerce, that a product embodying the White patent's cap in the 1990s, or at any time prior to the 2005 filing date of the Hoang patent application, would not have a protective lid or cover during shipment, storage and prior to use. Layton Dec. Ex. 1037, ¶ 24.

Hence, claim 10 is obvious in view of White, Harding, and Genatempo.

E. Claim 11 Is Obvious in Light of White and Paradis

Both White and claim 11 of the '846 patent disclose a cavity having an inner circumference and a thread having a length. It is not clear whether the length of the internal thread of White is less than the inner circumference. However, this is a trivial difference because a person of ordinary skill in the art would understand that this is a mere design choice dependent on the type of valve to which the cap is attached. It would be obvious for one of ordinary skill in the art to modify the cap in White to have a thread length less than an inner circumference in order to adapt to the external threads of the Harding publication, which appears to be the valve to which the '846 patent is adapted. Further, the Paradis patent teaches a valve with threading of a length that is less than the circumference of cylindrical connector. See partial luer threads 43 in Fig. 4a. (Ex. 1025, p. 5). See also the Examiner's

similar rejection of application claim 80 on the basis of Paradis (Ex. 1017, page 17). Finally, see Layton Dec. Ex. 1037, ¶ 29.

F. Claim 12 Is Obvious in Light of White and Harding

Claim 12 of the '846 patent calls for the cleaning solution of claim 10 to be an "antimicrobial agent." White discloses an antiseptic such as a povidone-iodine solution to keep the septum free of pathogens. One of ordinary skill in the art would recognize that a povidone-iodine solution is as an antimicrobial agent. In fact, the '846 patent identifies povidone iodine as an example of an antimicrobial agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

G. Claim 13 Is Obvious in light of White, Harding, Genatempo and Busch

Claim 13 of the '846 requires an antimicrobial agent comprised of at least one of chlorhexidine gluconate or chlorhexidine diacetate. White does not specifically disclose the use of chlorhexidine gluconate or chlorhexidine diacetate. However, it would have been obvious to one of ordinary skill to substitute a chlorhexidine gluconate for White's use of a povidone-iodine solution in view of the Busch publication's disclosure of a skin preparation package including chlorhexadine gluconate as an antiseptic solution. Moreover, one having ordinary skilled in the art would have seen chlorhexidine diacetate as an obvious substitute

for povidone iodine because the '846 patent discloses that “[a]ny number of microbial agents may be used” including “chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chlorizde, octenidine, antibiotic, etc.” Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).

H. Claim 14 Is Obvious in Light of White, Harding, Genatempo and Busch

Claim 14 of the '846 patent requires an alcohol-based cleaning solution. While White’s povidone iodine solution is not alcohol-based, it would have been obvious to one of ordinary skill in the art to substitute an alcohol-based solution for povidone iodine in view of Busch’s disclosure of isopropyl alcohol as an antiseptic solution. In addition, one skilled in the art would know that it was standard nursing practice, prior to the advent of protective caps, to wipe the access port septum with an alcohol wipe prior to accessing the septum.

I. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of the comments above.

CLAIM 10 White, Harding, and Genatempo	
CLAIM 10 (Reference numerals added)	PRIOR ART
A device 78 for maintaining a patient fluid line access valve A having an access portion A10 with an end face that includes a septum A6 and external threads A4 on the access portion A10 proximate the septum A6, the device comprising:	Figure 7 of White discloses an outer protective cap 78 for maintaining an access valve coupler 70, 82 for an indwelling catheter. The access valve 70, 82 has an end face that includes a septum 84 and external threads 74.
a housing 78 for covering the access portion A10 of the patient fluid line access valve A, the housing having an open end, a closed end, and a cavity, the housing including a thread 18 on an inner wall of the cavity for engaging the external threads A4 on the access portion A10 of the patient fluid line access valve A;	Referring to Fig. 7 of White, the outer protective cap 78 includes a housing for covering the proximal member or injection cap 82 of the coupler 70, 82, the housing having an open end, a closed end, and a cavity, the housing including internal threads 76 on an inner wall of the cavity for engaging the external thread 74 on the distal member 70 of the coupler.
a wet pad 80 impregnated with a cleaning solution prior to attachment of the housing 78 to the access portion A10 of the patient fluid line access valve A, the wet pad 80 being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads A4 of the access portion A10 of the	Referring to Fig. 7 of White, a sponge 80 saturated with an antiseptic is positioned within the cavity of cap 78 for contacting the septum 84 to disinfect the septum 84. Column 3, lines 39-45, and col. 2, lines 59-61, disclose that the antiseptic also flows along the walls of the proximal member 82. Also, col. 6, lines 58-66 teach that when the sponge 68 contacts septum 54, antiseptic material is <i>forced</i> within a space between proximal member 32 and outer protective cap 64 so that

<p>patient fluid line access valve A when the housing is positioned over and covers the access portion A10; and</p>	<p>the connection between female member 20 and proximal member 32 is bathed with antiseptic.” White also appreciates that threaded portions susceptible to pathogens. (See col. 2, lines 1-4, and col. 6, lines 58-66).</p> <p>Genatempo discloses with reference to Fig. 3, a protective cap 10 for a catheter that includes absorbent material 24 that retains an antiseptic or antibacterial agent. When the cap is placed on a catheter tube "an antibacterial effect is provided to main tubular member 40 of connector 32, <i>as well as threads 42 through migration of the antiseptic.</i>" Col. 3, lines 40-45 (emphasis added).</p>
<p>a lid 78a over the open end of the housing to seal the cavity with the wet pad 80 within the cavity and provide a moisture barrier, the lid 78a being removable to expose the wet pad 80 and allow insertion of the access portion A10 of the patient fluid line access valve A into the cavity so that the end face of the access portion A10 contacts the wet pad 80.</p>	<p>As noted above, the sponge 80 of White contacts the septum 84. The claim defines the end face to include the septum.</p> <p>Genatempo discloses in Fig. 1 a protective cap 10 having a <u>peelable lid 20</u>, as well as the cap 10 having an open end, a closed end, a cavity, an absorbent material 24 within the cavity and which retains volatile antibacterial agent, such as povidone iodine, and internal threads.</p>

CLAIM 11 (Reference numerals added)	PRIOR ART
The device of claim 10, wherein the cavity comprises an inner circumference 82 and the thread	White shows that the cavity comprises an inner circumference and that the thread 76 comprises a length.

18 comprises a length that is less than the inner circumference 82.	Paradis teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).
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CLAIM 12	PRIOR ART
The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.	White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55). The '846 patent identifies povidone iodine as an example of an antimicrobial agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

CLAIM 13	PRIOR ART
The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	<p>White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55).</p> <p>Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.</p>

CLAIM 14	PRIOR ART
The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.	<p>White discloses a disinfectant or antiseptic solution such as povidone-iodine solution or the like so the septum is free of pathogens. (col. 3, l. 37-57; col. 6, l. 52-55).</p> <p>Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.</p>

J. Claim 10 Is Obvious in View of Menyhay and Genatempo

Several substantial limitations of claim 10 of the '864 patent are disclosed by the Menyhay patent. Both Menyhay and claim 10 describe a disinfecting cap for an indwelling catheter access valve. (Menyhay, Ex. 1029, Abstract). As seen in Fig. 2 and the related text, each cap or cover 10 includes an open end, closed end and a cavity. A sponge 12 is located in the cover. The internal wall of the cover includes internal threads 15 for mating with the external threads 17 of an access valve or external injector port 19. The injector port 19 also includes an end face having a septum 18, wherein the threads 17 are proximate the septum 18. The cover also provides an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol. Col. 6, lines 47-49. Upon positioning the caps of Menyhay and claim 10 on an access valve, the sponges in both caps come

into contact with a septum and disperse aseptic solutions that bathe the septum and the surrounding structure of the access valve to prevent bacterial contamination. (Ex. 1029, sentence spanning columns 6 and 7). See also the O-ring 14 intended to seal the end of the cover 10. Col. 6, lines 59-61.

Menyhay and claim 10 differ in only three minor respects: Namely, the sponge 12 of Menyhay is not preloaded with the solution, whether the aseptic solution of Menyhay disinfects a portion of the external threads; and the absence of an express teaching of a peel-able lid on Menyhay's protective cap. The solution to these differences would have been readily obvious to a person of ordinary skill, given his or her's presumed knowledge of the teachings of the prior art Genatempo patent, as well as the inherent properties of the Menyhay cap.

First, the sponge 12 of Menyhay is not preloaded with the solution. Rather, Menyhay provides a breakable capsule 11 containing the solution. The capsule is ruptured when it is pressed firmly against projection 13 (Ex. 1029, col. 6, lines 49-51), thereby releasing the antiseptic agents inside to be soaked up by sponge 12 (Ex. 1029, col. 6, lines 63-64). However, Genatempo discloses that the absorbent material 24 is impregnated with a cleaning solution prior to attachment of the cap 10. See first paragraph of col. 3 and the Abstract (Ex. 1024). When the cover is removed, the patient is isolated from any potential hazard of the ruptured breakable capsule 11 only by the sponge 12. One skilled in the art would motivated to

consider the use of a preloaded absorbent material 24 over the use of a breakable capsule 11.

Second, Menyhay does not explicitly disclose that the aseptic solution in the sponge of the cap will contact "at least a portion of the external threads of the access portion" of the access valve, as specified by claim 10. This gap is amply filled by the Genatempo patent's express disclosure of a disinfecting cap similar to Menyhay that, when placed on a connector, provides "an antibacterial effect" to the connector "as well as threads 42 through migration of the antiseptic." (Ex. 1024, Col. 3, lines 43-45. One skilled in the art concerned with maintaining the access valve in an aseptic condition would readily be motivated to ensure that the arrangement of Menyhay would similarly provide such antibacterial effect to the external threads 74 of Menyhay.

Moreover, the person of ordinary skill would understand that the aseptic solution would also flow onto at least a portion of the external threads of the access valve given Menyhay's disclosures that an O-ring 14 is provided at or near the open end of the cylinder 10. (Ex. 1029, col. 6, lines 42-43), and that "When the present invention is screwed into place over the injection port, O-ring 14 creates a seal over the end of the port 19 (see Fig. 3). (Ex. 1029, col. 6, lines 59-61). It is readily apparent that the O-ring 14 is intended to retain the solution within the

cover. In fact, col. 7, lines 64-66 indicate that the “circumference of the inside of the cover should be slightly larger than the circumference of the stem of the port.”

It is also worth noting that the Patent Owner did not introduce a limitation requiring the disinfecting solution to contact the external threads of the access valve to the independent claims of the '864 application until January 2013. There is *no* disclosure in the written description of the '864 patent to support that limitation. Thus, a serious question exists as to whether this limitation would run afoul of the written description requirement of Section 112, unless it is inherent in the interface of the sponge of the disinfecting cap and the access valve septum that the disinfecting solution will reach the external threads. If that result is inherent in claim 10 of the '864 patent, it must also be inherent when the cap of Menyhay is placed on an access valve septum.

Third, Menyhay does not explicitly disclose a removable lid over the end of the disinfecting cap that engages the access valve to protect the aseptic solution prior to placing the cap on an access valve, as required by claim 10.⁴ But the use of a lid to preserve the solution, when using the preloaded sponge 24 of Genatempo, would have been obvious to one of ordinary skill in view of the Genatempo patent's disclosure of just such a lid for that purpose.

⁴ Menyhay does, however, disclose at Ex. 1029, col. 7, line 14-15 that a new sterile cover is contained in a sterile envelope.

Hence, claim 10 is obvious in view of Menyhay and Genatempo.

K. Claim 11 Is Obvious in Light of Menyhay and Paradis

Both Menyhay and claim 11 of the '846 patent disclose a cavity having an inner circumference and a thread having a length. It is not clear whether the length of the internal thread of Menyhay is less than the inner circumference. However, this is a trivial difference because a person of ordinary skill in the art would understand that this is a mere design choice dependent on the type of valve to which the cap is attached. It would be obvious for one of ordinary skill in the art to modify the cap in Menyhay to have a thread length less than an inner circumference. Further, as noted by the Examiner when rejecting the related claim 80, (Ex. 1017, p. 17, par. 43) the Paradis patent teaches a valve with threading of a length that is less than the circumference of cylindrical connector. See partial luer threads 43 in Fig. 4a. (Ex. 1025, p. 5).

L. Claim 12 Is Obvious in Light of Menyhay and Genatempo

Claim 12 of the '846 patent calls for the cleaning solution of claim 10 to be an "antimicrobial agent." Menyhay discloses a bactericidal (Ex. 1029, col. 6, line 49). Menyhay also discloses an antiseptic such as a povidone-iodine solution to keep the septum free of pathogens. One of ordinary skill in the art would recognize that a povidone-iodine solution is as an antimicrobial agent. In fact, the

'846 patent identifies povidone iodine as an example of an antimicrobial agent. See paragraph [0023] of the Hoang application publication. (Ex. 1002, p. 10).

M. Claim 13 Is Obvious in light of Menyahy, Genatempo and Busch

Claim 13 of the '846 requires an antimicrobial agent comprised of at least one of chlorhexidine gluconate or chlorhexidine diacetate. Menyahy does not specifically disclose the use of chlorhexidine gluconate or chlorhexidine diacetate. However, it would have been obvious to one of ordinary skill to substitute a chlorhexidine gluconate for Menyahy's use of a povidone-iodine solution in view of the Busch publication's disclosure of a skin preparation package including chlorhexadine gluconate as an antiseptic solution. Moreover, one having ordinary skilled in the art would have seen chlorhexidine diacetate as an obvious substitute for povidone iodine because the '846 patent discloses that "[a]ny number of microbial agents may be used" including "chlorhexidine gluconate, chlorhexidine diacetate, chloroxylonol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chlorizde, octenidine, antibiotic, etc." Paragraph [0023] of the Hoang application publication (emphasis added). (Ex. 1002, p. 10).

N. Claim 14 Is Obvious in Light of Menyahy and Genatempo

Claim 14 of the '846 patent requires an alcohol-based cleaning solution. Menyahy discloses isopropyl alcohol (Ex. 1029, col. 6, line 48).

O. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of the comments above in paragraphs J – N.

CLAIM 10 Menyhay, Harding, and Genatempo	
CLAIM 10 (Reference numerals added)	PRIOR ART
A device 78 for maintaining a patient fluid line access valve A having an access portion A10 with an end face that includes a septum A6 and external threads A4 on the access portion A10 proximate the septum A6, the device comprising:	Figs. 2, 3 and 6 of Menyhay show a cover 10 for maintaining an external injector port 19 for an indwelling catheter. The injector port 19 includes an access portion with an end face having a septum 18 and external threads 17 on the access portion proximate the septum 18.
a housing 78 for covering the access portion A10 of the patient fluid line access valve A, the housing having an open end, a closed end, and a cavity, the housing including a thread 18 on an inner wall of the cavity for engaging the external threads A4 on the access portion A10 of the patient fluid line access valve A;	Referring to Fig. 2 of Menyhay, the cover includes a housing 10 for covering the access portion, the housing having an open end, a closed end, and a cavity, the housing including internal threads 15 on an inner wall of the cavity for engaging the external thread 17 on the access portion of the injector port 19.
a wet pad 80 impregnated with a cleaning solution prior to attachment of the housing 78 to the access portion A10 of the patient fluid line access valve A,	Referring to Fig. 3 of Menyhay, a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol, the sponge 12 positioned within the cavity for contacting the

<p>the wet pad 80 being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads A4 of the access portion A10 of the patient fluid line access valve A when the housing is positioned over and covers the access portion A10; and</p>	<p>end face 18 to disinfect the end face.</p> <p>Genatempo discloses that the absorbent material 24 is impregnated with a cleaning solution prior to attachment of the cap 10. See first paragraph of col. 3 and the Abstract.</p> <p>Col. 6, lines 60-61 of Menyhay disclose with reference to Fig. 3 that the O-ring 14 creates a seal over the end of the port 19. Fig. 3 shows that the seal is intended to retain the solution from the sponge 12 from moving past the o-ring 14. In addition, Col. 7, lines 64-66 indicate that the "circumference of the inside of the cover should be slightly larger than the circumference of the stem of the port." The sentence spanning columns 5 and 6 indicates that the cover provides a "continuous aseptic immersion (bathing) of the injection port." Col. 7 lines 4-6 indicate that the cover aseptically cleanses the "surface of an injection port."</p> <p>Genatempo discloses with reference to Fig. 3, a protective cap 10 for a catheter that includes absorbent material 24 that retains an antiseptic or antibacterial agent. When the cap is placed on a catheter tube "an antibacterial effect is provided to main tubular member 40 of connector 32, <i>as well as threads 42 through migration of the antiseptic.</i>" Col. 3, lines 40-45 (emphasis added).</p>
<p>a lid 78a over the open end of the housing to seal the cavity with the wet pad 80 within the cavity and provide a moisture barrier, the lid 78a being removable to expose the wet pad 80 and allow insertion of</p>	<p>Genatempo shows in Fig. 1, in conjunction with a preloaded absorbent material 24, a protective cap 10 having a <u>peelable lid 20</u>, as well as the cap 10 having an open end, a closed end, a cavity, the absorbent material 24 within the cavity and which retains volatile antibacterial agent, such as povidone iodine,</p>

the access portion A10 of the patient fluid line access valve A into the cavity so that the end face of the access portion A10 contacts the wet pad 80.	and internal threads.
---	-----------------------

CLAIM 11 (Reference numerals added)	PRIOR ART
The device of claim 10, wherein the cavity comprises an inner circumference 82 and the thread 18 comprises a length that is less than the inner circumference 82.	Menyhay shows that the cavity comprises an inner circumference and that the thread 15 comprises a length. Paradis teaches a valve having threading of a length that is less than the circumference of cylindrical connector (see partial luer threads 43 on cylindrical cap 40 in Fig. 4a).
CLAIM 12	PRIOR ART
The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.	Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.

CLAIM 13	PRIOR ART
The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.

	Busch teaches in paragraph [0026] a skin preparation package including a swab, sponge etc. that is soaked in an antiseptic solution such as chlorhexadine gluconate with isopropyl alcohol, etc.
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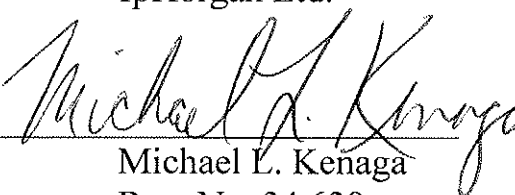
CLAIM 14	PRIOR ART
The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.	Menyhay discloses a sponge 12 saturated with an antiseptic, bactericidal and virucidal solution consisting of povidone iodine and isopropyl alcohol.

IX. CONCLUSION

For the reasons described above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 10-14 (application claims 79-83) of the '864 Patent. Accordingly, *inter partes* review of claims 10-14 of the '864 Patent is respectfully requested.

Dated: June 23, 2014

Respectfully Submitted,
IpHorgan Ltd.

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Case IPR2014-00880

ATTORNEYS FOR PETITIONER

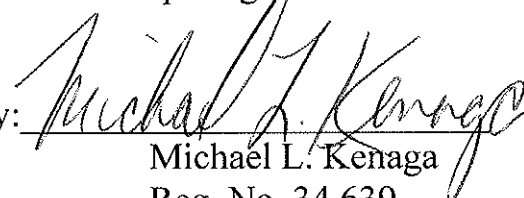
**CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)**

Pursuant to 37 C.F.R. §§ 42.8(e) and 42.105(b), the undersigned certifies that on the 23rd day of June 2014, a complete and entire copy of this Corrected Petition for *Inter Partes* Review (excluding the exhibits that were previously provided with the original Petition) was provided via Courier, postage prepaid, to the Patent Owner by serving the correspondence address of record for the '864 Patent:

David W. Highet, VP & Chief IP Counsel
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(Kirton & McConkie)
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Respectfully Submitted,
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Case IPR2014-00880

ATTORNEYS FOR PETITIONER

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
Filed: June 3, 2014

**POWER OF ATTORNEY
UNDER 37 C.F.R. §42.10**

Patent Owner Becton, Dickinson and Company hereby appoints the following attorneys and/or agents to prosecute the above captioned *Inter Partes* Review and transact all business in the U.S. Patent and Trademark Office connected herewith:

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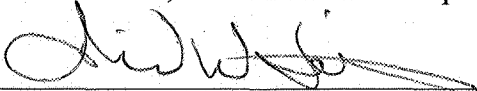
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The individual listed below has the authority to execute this document on behalf of Becton, Dickinson and Company.

For: Becton, Dickinson and Company



Name: David W. Highet
Title: VP and Chief Intellectual Property
Counsel

Dated: JUNE 19, 2014

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
Filed: June 3, 2014

**PATENT OWNER MANDATORY NOTICE
INFORMATION UNDER 37 C.F.R. §42.8**

MANDATORY NOTICES FROM BECTON, DICKINSON AND COMPANY

Pursuant to 37 C.F.R. § 42.8, Becton, Dickinson and Company respectfully submits the following Mandatory Notices.

I. REAL PARTY IN INTEREST

Patent Owner Becton, Dickinson and Company is the real party in interest. Becton, Dickinson and Company is the sole owner of U.S. Patent No. 8,740,864 (“the ’864 patent”) by assignment filed on November 17, 2005 at Reel 017252 Frame 0614.

II. RELATED MATTERS

The following litigation matters would affect or could be affected by a decision in this proceeding: *Excelsior Medical Corp. v. Ivera Medical Corp. and Becton, Dickinson and Co.*, Case No. 1:2014-cv-03502 (D.N.J.); *Catheter Connections, Inc., v. Ivera Medical Corp. and Becton, Dickinson and Co.*, Case No. 2:2014-cv-03512 (D.N.J.); *Hospira, Inc. v. Ivera Medical Corp. and Becton, Dickinson and Co.*, Case No. 2:2014-cv-03513 (D.N.J.); *Ivera Medical Corp. and Becton, Dickinson and Co. v. Excelsior Medical Corp., Covidien LP, and Covidien Sales, LLC*, Case No. 3:14-cv-01348 (S.D. Cal.); *Ivera Medical Corp. and Becton, Dickinson and Co. v. Catheter Connections, Inc.*, Case No. 3:14-cv-01346 (S.D. Cal.); *Ivera Medical Corp. and Becton, Dickinson and Co. v. Hospira, Inc.*, Case No. 3:14-cv-01345 (S.D. Cal.).

III. COUNSEL

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David L. Cavanaugh, Reg. No. 36,476

Back-up Counsel:

Heather M. Petruzzi, Reg. No. 71,270

IV. SERVICE INFORMATION

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V. **PATENT OWNER PRELIMINARY RESPONSE**

Patent Owner Becton, Dickinson and Company reserves the right to file a preliminary response by September 16, 2014 pursuant to the deadline provided by 37 C.F.R. § 42.107 and Paper No. 4.

Dated: June 24, 2014

Respectfully submitted,

/David L. Cavanaugh/

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Attorneys for Patent Owner
Becton, Dickinson and Company

CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2014, I caused a true and correct copy of the foregoing documents:

- **MANDATORY NOTICES**
- **POWER OF ATTORNEY**

to be served electronically on the following attorneys of record:

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/Heather M. Petruzzi/
Heather M. Petruzzi

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

Entered: June 25, 2014

Before Andrew Kellogg, *Trial Paralegal*

NOTICE ACCEPTING CORRECTED PETITION

The corrected petition filed on June 23, 2014 in the above proceeding is accepted.

The parties are reminded that unless otherwise permitted by 37 C.F.R. § 42.6(b)(2), all filings in this proceeding must be made electronically in the Patent Review Processing System (PRPS), accessible from the Board Web site at <http://www.uspto.gov/PTAB>. To file documents, users must first obtain a user ID and password by registering with PRPS. Information

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regarding how to register with and use PRPS is available at the Board Web site.

If there are any questions pertaining to this notice, please contact Andrew Kellogg at 571-272-5366 or the Patent Trial and Appeal Board at 571-272-7822.

Case IPR2014-00880

Patent 8,740,864

For PETITIONER:

Michael Kenaga
Sean Swidler
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For PATENT OWNER:

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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

PETITIONER'S UPDATED MANDATORY NOTICE DISCLOSURE
PURSUANT TO 37 C.F.R. § 42.8(a)(3)

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Petitioner Excelsior Medical Corporation hereby updates the following disclosures of its mandatory notices pursuant to 37 C.F.R. § 42.8(a)(3):

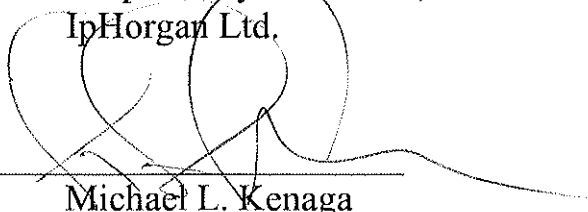
A. Real Party-In-Interest

Petitioner hereby updates its identification of real parties-in-interest to further include Covidien LP, and Covidien Sales, LLC.

Dated: July 3, 2014

Respectfully Submitted,
IpHorgan Ltd.

By: _____


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Case IPR2014-00880

ATTORNEYS FOR PETITIONER

Petitioner's Updated Mandatory Notice Disclosure for *Inter Partes* Review of U.S. Patent No. 8,740,864

CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)

Pursuant to 37 C.F.R. §§ 42.8(e) and 42.105(b), the undersigned certifies that on the 3rd day of July 2014, a complete and entire copy of this Updated Mandatory Notice Disclosure has been served electronically to the counsel of record for Patent Owner via email addresses:

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Heather Petruzzi
Wilmer Cutler Pickering Hale and Dorr LLP
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Case IPR2014-00880

ATTORNEYS FOR PETITIONER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BECTON, DICKINSON AND COMPANY
Patent Owner

Case IPR2014-00880
Patent 8,740,864

PATENT OWNER'S PRELIMINARY RESPONSE UNDER

37 C.F.R § 42.10

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ii)	Nothing in the File History required claim 10 to recite the rotation of external threads for patentability	12
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I. Introduction

The Petitioner attempts to burden the Patent Owner with a perfunctory *Inter Partes* Review Petition that rehashes the same arguments very recently rejected by the Office. Under 35 U.S.C. § 325(d), the Board has discretion to reject a Petition for *Inter Partes* Review, if the “same or substantially the same prior art or arguments [were] previously [] presented” to the Office. 35 U.S.C. § 325(d). Here, each of the arguments set forth in the Petition relies on the same art (or in one case, a cumulative secondary reference) considered by the Office when it issued U.S. Patent No. 8,704,864 (“the ’864 patent”) (Ex. 2001). The ’864 patent issued on the same day that the Petition was filed. Further, the expert declaration that purportedly supports the Petition does not address several of the proposed grounds, and where it does address the prior art, it does not provide any new evidence or perspective. The Board should exercise its discretion in this case and reject the Petition under 35 U.S.C. § 325(d).

II. The Petition Should Properly be Denied Under 35 U.S.C. § 325(d)

A Petition is properly denied where the Petitioner fails to direct the Board to any new evidence establishing a reasonable likelihood that the Petitioner will prevail on at least one claim. *See e.g.*, IPR2013-00494 Decision on Institution at 20. The Board previously exercised its authority, and denied an IPR Petition filed by the *same Petitioner*, Excelsior, against a patent in the same technology area,

where the Petitioner took the same lackluster approach to the Petition and submitted arguments for one ground that had previously been considered by the Office. *See id.*; *see also* IPR2014-00315 at 13 (denying the Petition when the same '192 publication and challenge to the priority claim was already considered by the examiner during prosecution). The facts of the prior Excelsior case were less egregious than the instant case because here the Petitioner relies on prior art and arguments previously before Office for *all* of the asserted grounds.

Additionally, the circumstances of the present Petition are clearly distinct from other unsuccessful attempts by Patent Owners to persuade the Board to exercise its discretion under 35 U.S.C. § 325(d). Unlike, for example, IPR2013-00038, where the Board determined that the Petitioner had not alleged “the examiner considered ‘substantially the same . . . arguments,’” (IPR2013-00038 Decision on Institution at 6), here, the Petitioner *has* presented substantially the same arguments, and has not included *any* new, non-cumulative evidence. Indeed, for some of the asserted grounds, the Petitioner has not submitted any evidence at all.

A. The Petition presents the same art previously presented to the Office

The Petition only relies on two primary references, White and Menyhay, both of which were extensively applied by the examiner during prosecution of the '864 patent as the basis for all of the grounds presented in the Petition. (Petition at

4-5.) Specifically, the Petition challenges claims 10-14 based on the following grounds:

- A. Ground A - Claim 10 - White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- B. Ground B - Claim 11 - White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- C. Ground C - Claim 12 - White (Ex. 1021) in view of Harding (Ex. 1022) and Genatempo (Ex. 1024).
- D. Ground D - Claim 13 - White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- E. Ground E - Claim 14 - White (Ex. 1021) in view of Harding (Ex. 1022), Genatempo (Ex. 1024), and Busch (Ex. 1026).
- F. Ground F - Claim 10 - Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).
- G. Ground G - Claim 11 - Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Paradis (Ex. 1025).
- H. Ground H - Claim 12 - Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).
- I. Ground I - Claim 13 - Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024), and Busch (Ex. 1026).
- J. Ground J - Claim 14 - Menyhay (Ex. 1029) in view of Genatempo (Ex. 1024).

For ease of discussion, the Office Actions and Responses during prosecution of the '864 patent will be referenced as follows:

- “First Office Action” – Office Action of Nov. 25, 2009 (Ex. 1006)
- “First Response” – Response of Feb. 19, 2010 (Ex. 1007)

- “Second Office Action” – Office Action of June 11, 2010 (Ex. 1008)
- “Second Response” – Response of Nov. 12, 2010 (Ex. 1009)
- “Third Office Action” – Office Action of Apr. 10, 2012 (Ex. 1010)
- “Third Response” – Response of June 28, 2012 (Ex. 1012)
- “Fourth Office Action” – Office Action of Sep. 25, 2012 (Ex. 1013)
- “Fourth Response” – Response of Jan. 24, 2013 (Ex. 1015)
- “Fifth Office Action” – Office Action of Aug. 15, 2013 (Ex. 1017)
- “Fifth Response” – Response of Nov. 14, 2013 (Ex. 1018)
- “Notice of Allowance” – Notice of Allowance of Jan. 21, 2014 (Ex. 1019)

Notably, the Office applied at least one of White or Menyhay as an anticipatory or primary reference in *each* of the five Office Actions prior to allowance of the ’864 patent. (First Office Action at 4-5¹ (discussing Menyhay) (Ex. 1006); Second Office Action at 3-6 (discussing White) (Ex. 1008); Third Office Action at 4-6 (discussing White) (Ex. 1010); Fourth Office Action at 5-6 (discussing Menyhay) (Ex. 1013); Fifth Office Action at 7-20 (discussing White) (Ex. 1017).) Additionally, the Office applied secondary references Genatempo, Paradis and Busch during prosecution for the same or substantially the same

¹ All citations to exhibits reference the page number of the exhibit, which may differ from the page number of the original document.

teachings for which the Petitioner relies upon those references in the Petition. (First Office Action at 4 (discussing Genatempo) (Ex. 1006); Third Office Action at 5-6 (discussing Busch) (Ex. 1010); Fourth Office Action at 7 (discussing Busch) (Ex. 1013); Fifth Office Action at 11-13, 17-18 (discussing Paradis and Busch) (Ex. 1017).)

Harding is the only reference in the Petition that was not before the Office and applied during prosecution. (Petition at 1.) The Petition cites Harding as a secondary reference (with White as a primary reference) for the limited purpose of disclosing the location of external threads on an access valve. (Petition at 23-24.) However, this limitation was never identified during prosecution as a missing limitation in the prior art. As discussed in more detail below, the Office allowed claim 10 after considering the disclosure of Menyhay and White, including their disclosure of the location of external threads on an access valve, and allowed claim 10 (original claim 79) because the prior art did not teach or suggest the combination of claim elements. (See Interview Summary of April 7, 2014 at 4 (Ex. 1020).)

The Petition does not provide any argument or cite any expert testimony describing why the examiner's obviousness combinations and subsequent allowance over those combinations were improper. Instead, the Petition cites White, the same primary reference that was already applied during prosecution,

and relies on a combination with Harding to disclose “an access valve with external threads near the septum.” (Petition at 22-23.) The Petition itself does not provide a citation to the Harding reference, instead only citing the Layton Declaration, which in turn only cites Fig. 4 of Harding for this point. (*Id.* at 23.) Additionally, Harding is not cited in the claim 10 claim charts at all. (*Id.* at 29-30.) In fact, the claim 10 chart only cites White as disclosing this limitation, stating, “The access valve 70, 82 has an end face that includes a septum 84 and external threads 74.” (*Id.* at 29.) Thus, it appears that the Petitioner agrees that White discloses the location of external threads on an access valve as recited in claim 10, which highlights the secondary and confirms the cumulative role of Harding in the Petition.

The addition of Harding does not rise to the level of new argument because it is merely cumulative of the prior art applied during prosecution, specifically Menyhay and White. First, by Petitioner’s own admission, Harding is cumulative of Menyhay. The Petitioner relies on Menyhay in ground F to disclose the ***same limitation***, the location of external threads on an access valve, as the Petitioner relies upon Harding in ground A. For example, the Petitioner states that Menyhay discloses an injector port with “threads 17 [that] are proximate the septum 18.” (Petition at 32.) Thus, the Petition cites Harding and Menyhay to disclose the

same claim limitation, and it does not cite Harding to disclose any other claim limitation, further highlighting the cumulative role of Harding.

Moreover, during prosecution the Office cited Menyhay as disclosing the exact same limitation regarding the location of the external threads on an access valve as recited in issued claim 10.² (See Fourth Office Action at 5-6 (rejecting claim 62 in view of Figs. 3 and 5 of Menyhay) (Ex. 1013).) Because both the Petitioner and the Office cite Menyhay as disclosing the same claim limitation for which the Petitioner cites Harding, and the Petitioner does not cite Harding to disclose any other claim limitation, Harding's disclosure of the location of the external threads on an access valve is cumulative to Menyhay.

Additionally, the Office also cited White during prosecution as disclosing the same limitation for which the Petitioner is now relying on Harding. The examiner rejected original claim 1 in view of White when it recited the same

² When the Office rejected original claim 62 in view of Menyhay, the claim recited the exact language of issued claim 10: an access valve "having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum." (*Compare* Third Response, Claim 62 at 4 (Ex. 1012) *with* '864 patent, claim 10 at 6:3-26 (Ex. 2001).)

location of the threads on an access valve as issued claim 10.³ (*See* Third Office Action at 4-5 (Ex. 1010).) The Petitioner does not state anywhere in the Petition,⁴ and Dr. Layton does not state anywhere in his declaration, that the Office's interpretation was incorrect with respect to the disclosure of White. Thus, the Office already cited White as disclosing the same claim limitation for which the Petitioner cites Harding, and the Petitioner does not cite Harding to disclose any other claim limitation. As a result, arguments based on Harding are at least substantially the same, if not identical, to arguments previously considered by the Office.

Because all of the art relied upon in the Petition was already considered by the examiner or is cumulative of references considered by the examiner, the

³ When the Office rejected original claim 1 in view of White, claim 1 recited the exact language in issued claim 10: an access valve "having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum." (*Compare* Second Response, claim 1 at 2 (Ex. 1009) *with* '864 patent, claim 10 at 6:3-26 (Ex. 2001).)

⁴ As discussed above, the claim 10 chart fails to cite Harding and only cites White as disclosing this limitation. (Petition at 29.) Thus, it appears that the Petitioner agrees that White discloses this limitation.

Petition fails to provide new evidence establishing a reasonable likelihood that the Petitioner will prevail on at least one claim.

B. Grounds in the Petition are nothing more than a regurgitation of the same or substantially the same arguments already considered by the Office

Grounds A-J should be rejected under 35 U.S.C. § 325(d), because they constitute nothing more than a regurgitation of the same or substantially the same arguments that were previously considered by the Office.

1. Independent Claim 10

a) The Office has already considered the Petitioner's arguments in Ground A, Claim 10 - White in view of Harding and Genatempo

Ground A of the Petition challenges claim 10 under 35 U.S.C. §103 using White in view of Harding and Genatempo.⁵ (Petition at 21-26, 29-30.) The Office already applied the combination of **White and Genatempo** in during prosecution for the *same teachings* as the Petitioner relies on the Petition. (Fifth Office Action

⁵ The Petition also argues that “there is a serious question” as to whether claim 10 is supported by written description. (Petition at 25.) Pursuant to 35 U.S.C. § 311, a petition to institute *inter partes* review is limited to challenging a claim “only on a ground that could be raised under section 102 or 103.” Thus, the written description arguments under 35 U.S.C. § 112 presented at page 25 of the Petition are impermissible and are not appropriate for BD to address at this time.

at 14-15 (rejecting claim 79 based on White in view of Genatempo) (Ex. 1017).)

As shown below, the underlined and crossed out portions indicate the only differences between the version of claim 79 that was rejected in the Fifth Office Action under White and Genatempo, and the version of the claim that issued as claim 10.

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.

(Fifth Response at 3-4 (Ex. 1018).) Thus, the Patent Office has already considered White in view of Genatempo for the majority of the claim limitations and ultimately found the claim patentable over these references.

With respect to the underlined limitations that were added by amendment, those limitations were present in different original claims, and addressed by the

Office using White and Genatempo. For example, the limitation of “disinfect[ing] the face and at least a portion of the external threads of the access portion of the patient fluid line access valve” was present in original claim 69 (Fourth Response at 2 (Ex. 1015)) and rejected under the combination of Genatempo and White. (Fifth Office Action at 7-9 (relying on White for disclosure of a connector that is a patient fluid line access valve having an end face that includes a septum) (Ex. 1017).) Therefore, the limitations in claim 10 were already considered and allowed over the combination of White and Genatempo.

The Petitioner concedes that White fails to disclose three limitations of claim 10, including the location of the external threads of the access valve, disinfecting a portion of the external threads, and a peel-able lid, and relies on Genatempo and Harding to cure the deficiencies. (Petition at 22.) The Petitioner cites to Harding for a very limited purpose of disclosing the first limitation (Petition at 23), the location of the threads on a connector, but as previously discussed, Harding is merely cumulative of other references applied by the Office and the Petitioner for that limitation, including White and Menyhay. Thus, Harding does not provide any new, non-cumulative disclosure over the references previously considered by the Office. With respect to the second and third limitations, the Petitioner relies on Genatempo for its teaching of disinfecting a portion of the external threads on the access portion and a peel-able lid. (Petition at 22.) As discussed above, the Office

already applied Genatempo in combination with White for these precise limitations during prosecution. (Fifth Office Action at 8, 15 (Ex. 1017).) Thus, Ground A presents nothing new that is not the same or substantially the same as what was previously considered and decided by the Office.

i) The Layton Expert Declaration does not provide any new evidence

The Layton Declaration discusses the combination of White, Harding and Genatempo at paragraphs 21-28 (Layton Decl. at ¶21-28 (Ex. 1037)) and does not add any additional argument not duplicative of what is in the Petition and what was considered during prosecution. Additionally, the Layton declaration does not cite any new evidence not previously before the Office that would render the declaration a substantially new argument.

ii) Nothing in the File History required claim 10 to recite the rotation of external threads for patentability

Petitioner attempts to argue that the Office erred in allowing claim 79 (issued claim 10) because the Applicant did not amend claim 79 to require rotation of the internal threads of the cap with the external threads of the access valve to cause the wet pad to come into contact with the septum, and the examiner did not cite White. (Petition at 16.) However, the examiner already addressed the Petitioner's arguments.

Specifically, the Interview Summary of April 7, 2014 addresses the “statement of the reasons for allowance as it would apply to allowed independent claim 79,” and the fact that claim 79 does not specifically require rotational movement to cause disinfecting. (Interview Summary of April 7, 2014 at 4 (Ex. 1020).) The examiner explicitly agreed with the Applicant that claim 79 is allowable even though it did not specifically require rotational movement to cause disinfecting. (*Id.*) The examiner noted:

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.

(*Id.*) As previously discussed, the examiner clearly applied White to the claims.

As articulated by the examiner, allowance is based on the totality of the prosecution, not just the reasons for allowance articulated. (*Id.*) Thus, the prosecution history does not support Petitioner’s assertion that claim 10 is unpatentable because it does not specifically recite that rotational movement of the cap disinfects and end face of the septum and at least a portion of the external threads.

b) The Office has already considered the Petitioner's arguments in Ground F, Claim 10 – Menyhay in view of Genatempo

Ground F of the Petition, challenges claim 10 under 35 U.S.C. §103 using Menyhay in view of Genatempo.⁶ (Petition at 32-36, 38-40.) The Office already considered the limitations in claim 10 with regard to Menyhay and Genatempo during prosecution, and determined that claim 10 is patentable over their disclosures. Menyhay was applied in two Office Actions against the same (or substantially similar) language as limitations in claim 10, and the claims ultimately issued over Menyhay. (First Office Action at 4-5 (Ex. 1006); Fourth Office Action at 5-6 (Ex. 1013).) Specifically, the Office discussed Menyhay as follows:

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 .

⁶ Though the claim chart at pages 38-40 of the Petition includes Harding in the heading, Harding is not recited in the body of the claim chart, nor is it discussed in the Claims Challenged on the Basis of Specific Prior Art Section IV and The Obviousness Framework Section VIII(J). Thus it is presumed that Harding is not part of the proposed ground.

. . 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). . . .

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). . . .

(Fourth Office Action at 5-6 (emphasis added) (Ex. 1013).) In direct response to the above rejection, the Applicant added claim 79 (issued claim 10) to distinguish Menyhay. (Fourth Response at 3-4 (Ex. 1015); *see also* Interview Summary of Jan. 23, 2013 at 2 (Ex. 1014).) Applicant submitted that “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.” (Fourth Response at 7 (Ex. 1015).) In light of that response, the Office subsequently withdrew the rejection. (Fifth Office Action at 2 (Ex. 1017).) For at least these reasons, the Office has previously considered the same or substantially the same evidence as presented in the Petition for claim 10 with respect to Menyhay, and determined the claims were patentable over its disclosure.

As with White, the Petitioner concedes that Menyhay lacks three limitations of claim 10 and relies on Genatempo for these limitations. (Petition at 33-35.) This is not a new argument either, because Genatempo too was applied during prosecution for the same three limitations: preloading a disinfectant cap with cleaning solution, aseptic solution contacting a portion of the external threads of the access portion, and a peel-able lid. (See Fifth Office Action at 7-8, 15 (Ex. 1017).) Because the Office already considered the question of whether claim 10 is patentable in view of Menyhay and Genatempo, the Petition adds no new argument not previously presented to the Office.

i) The Layton Expert Declaration does not address Menyhay

The Layton Declaration does not add any new evidence with regard to Menyhay for the simple reason that the Layton Declaration *does not mention Menyhay*. Therefore, the grounds in the Petition based on Menyhay are completely unsupported by an expert declarant or any new evidence.

2. Dependent claims

The secondary references relied upon in the dependent claims are plagued by the same flaws as White and Menyhay. The Office *already considered* secondary references Paradis and Busch, for the *same* disclosures now relied upon in the Petition for the dependent claims.

a) The Office already considered the same art and the same arguments as those presented in the dependent claim grounds

i) Claim 11 – Grounds B and G

Petitioner concedes that Paradis was previously applied by the Patent Office for the very same disclosure it relies upon in the Petition with regard to claim 11(original claim 80) —the length of the threading inside the cap. (Petition at 26-27 (*citing* Ex. 1017 at 17).) Because by Petitioner’s own admission, grounds B and G do not present any new arguments not previously before the Office, they should be rejected pursuant to 35 U.S.C. § 325(d).

Moreover, as discussed in section II(B)(1), the limitations of claim 10 from which claim 11 depends were previously presented to the Office during prosecution. Because the Office already considered the question of whether the limitations in claim 11, particularly the limitation directed to the length of the threads, are obvious in view of White, Menyhay, Genatempo, and Paradis, or substantially the same references, the Petition adds no new argument and grounds B and G should not be instituted.

ii) Claim 12 – Grounds C and H

The Patent Office previously considered the primary references for their disclosure of the limitations recited in dependent claim 12. Specifically, claim 12 (original claim 81) adds the limitation that the cleaning solution comprises an

antimicrobial agent. ('864 patent at 6:30-31 (Ex. 2001).) Both grounds C and H rely on their primary reference, White or Menyhay, respectively, for disclosure of the additional limitation in claim 12. (Petition at 27, 36-37.)

With regard to ground C, the Office applied White and Genatempo for the limitation of an antimicrobial agent, stating that “White et al further discloses the cleaning solution comprises an antimicrobial agent.” (Fifth Office Action at 15 (Ex. 1017).) With regard to ground H, the Office Applied Menyhay for the limitation of an antimicrobial agent in the Fourth Office Action, stating “[w]ith regards to claim 65, see 11 containing antibacterial agent.” (Fourth Office Action at 5-6 (*citing* Menyhay) (Ex. 1013).) Moreover, as discussed in section II(B)(1), the limitations of claim 10 from which claim 12 depends were previously presented to the Office during prosecution. Because the Office already considered the question of whether the limitations in claim 12, particularly the limitation directed to an antimicrobial agent, are disclosed or obvious in view of White, Menyhay, and Genatempo, or substantially the same references, and allowed claim 12 over their disclosure, the Petition adds no new argument and should be rejected.

iii) Claims 13 and 14 – Grounds D, E and I

The Office previously considered Busch for its disclosure of an antimicrobial agent comprising at least one of chlorhexidine gluconate and chlorhexidine diacetate, as recited in claim 13 (original claim 82), and a cleaning

solution that is alcohol-based, as recited in claim 14 (original claim 83). ('864 patent at 6:32-36 (Ex. 2001).) Each of grounds D, E and I rely on Busch for disclosure of the additional limitations in claims 13 and 14. (Petition at 27-28, 31-32, 37, 40-41.) The Office applied Busch for the teaching of an antimicrobial agent that comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate, and that the cleaning solution is alcohol-based, stating that “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.” (Fifth Office Action at 18 (Ex. 1017).)

As discussed in section II(B)(1) and above, the limitations of claims 10 and 12, from which claims 13 and 14 depend, were previously presented to the Office during prosecution. Because the Office already considered the question of whether the additional limitations claims 13 and 14, are disclosed or obvious in view of White, Menyhay, Genatempo, and Busch, or substantially the same references, and allowed claims 13 and 14 over their disclosure, the Petition adds no new argument and should be rejected.

iv) Claim 14 – Ground J

Ground J relies on Menyhay for disclosure of an alcohol-based cleaning solution. The Office previously cited Menyhay for its teaching of a solution containing isopropyl alcohol. (First Office Action at 4 (*citing* Menyhay at 6:44-67))

(Ex. 1006).) Because the Office already considered the question of whether the additional limitation claim 14 is disclosed or obvious in view of Menyhay, and allowed claim 14 over its disclosure, the Petition adds no new argument and should be rejected.

III. Individual Grounds of Unpatentability are Deficient

A. Proposed grounds for certain dependent claims do not address all of the prior art references from the independent claims

The Petition fails to address each limitation of independent claims from which the subsequent claims depend. 35 U.S.C. §112, ¶ 4 states “a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.” As explained below, the Petition is deficient because at several points, it fails to properly refer back to independent claims, and in so doing, does not address the combination of references necessary to find dependent claims obvious.

Grounds B and G, directed toward claim 11, are deficient because they do not address the limitations of claim 10, from which claim 11 depends. (*See* Petition at 26-27, 30-31, 36, 40.) Namely, they fail to cite to the combinations of White, Harding and Genatempo or Menyhay and Genatempo which were relied upon for independent claim 10. Indeed, grounds B and G do not reference

Genatempo at all, and as a result do not provide any discussion or analysis as to why one would add Paradis to the combinations recited for claim 10. For at least this reason, grounds B and G should be denied. (*Id.*)

Grounds C and H, directed toward claim 12, also fail to include discussion of Genatempo, one of the references relied upon for independent claim 10. (Petition at 27, 31, 36-37, 40.) The grounds directed toward claims 13 and 14, D and E, are also deficient because though they mention each of the references relied upon in independent claim 10 in their headings, they do not discuss claims 10 and 12, from which claims 13 and 14 depend, or why it would be obvious to add Busch to the combinations relied upon for those claims. (Petition at 27-28, 31-32.)

B. Grounds B, D, E, H and I fail to provide an obviousness analysis guided by *KSR*.

Grounds B and H directed to claim 11, grounds D and I directed to claim 13, and ground E directed to claim 14, are deficient because they provide an inadequate rationale for combining the references. With regard to grounds B and H (claim 11), the Petition's only rationale for its assertion of obviousness is that the length of the thread is a "design choice dependent on the type of valve to which the cap is attached." (Petition at 26-27, 36.) With respect to ground B, the Petition generally cites to the Layton Declaration at ¶ 29, but the declaration makes a conclusory statement that the design of a thread that is less than the inner circumference of the cavity would have been obvious because "the threads are

more exposed to the antiseptic.” (Layton Decl. at ¶ 29 (Ex. 1037).) The Petition is completely silent as to why this is an obvious design choice with respect to ground H. Further, the Petition does not provide any analysis as to how that purported design choice would be obvious in light of the combination of references relied upon for the independent claim.

With regard to grounds D and I directed to claim 13, the Petition relies on a single conclusory statement that one would have seen the specific compound recited in claim 13 as an “obvious substitute,” but does not provide any obviousness analysis or rationale guided by *KSR* as to why that would be so. (Petition at 27-28, 37.) Instead, the Petition improperly cites the ’864 specification itself for support, despite the fact that the disclosure in the specification is part of the invention and cannot be used to as a basis for making an obvious substitution. (*Id.*)

Ground E, directed toward claim 14 based on the combination of White, Harding, Genatempo, and Busch is deficient because it also makes only conclusory statements about the disclosure in Busch, without providing any analysis or evidence stating why it would have been obvious to one of ordinary skill in the art to substitute an alcohol-based solution for povidone iodine in view of Busch. (Petition at 28.) For at least this reason, grounds B, D, E, H and I should be denied.

IV. Claim Construction

A claim subject to *inter partes* review is given its “broadest reasonable construction in light of the specification in which it appears.” 37 C.F.R. § 42.100(b). The broadest reasonable construction is the broadest reasonable interpretation of the claim language. *See In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 2004). Solely for the purposes of this proceeding, the following discussion proposes BD’s constructions for the terms identified by the Petitioner only and identifies support for these constructions. Any claim term not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art.

A. “access portion”

Claim 10 recites “a patient fluid line access valve having an access portion.” The proposed construction of the term “access portion” is *the exposed surface of the septum and at least a portion of the exposed surface of the housing that surrounds the septum*. (See ’864 patent at 2:3-7 (“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.”); claim 10 preamble (“an access portion with an end face that includes a septum and external threads on the access portion proximate the septum”) and claim 10 (“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...”); Fig. 1 (Ex. 2001).) The specification describes this term to include the exposed surface of the septum and the exposed surface of the housing that surrounds the septum, which is consistent with the use of the term in claim 10.

B. “length”

Dependent claim 11 recites “the thread comprises a length that is less than the inner circumference.” The proposed construction of the term “length” is *the distance or measurement from one end to the other*. (See, e.g., ’864 patent at 5:4-6 (Ex. 2001); Oxford Dictionary at 815 (Ex. 2002); Longman Dictionary at 520 (Ex. 2003).) The Petitioner’s proposed construction introduces the concepts of threads and the cavity into the definition of a term, length, that has a plain meaning devoid from these concepts.

C. “cleaning solution”

Claims 10, 12, and 14 recite the term “cleaning solution,” which should be given its plain meaning to one of ordinary skill in the art in view of the specification and does not require a separate construction.

D. “lid”

Claim 10 recites the term “lid,” which should be given its plain meaning to one of ordinary skill in the art in view of the specification and does not require a separate construction.

V. Definition of One of Ordinary Skill in the Art

The Petition proposes a definition of one of ordinary skill in the art that is overly narrow. Instead, the definition should include a combination of education or experience in engineering or design and should also take into consideration people with knowledge developing or using patient fluid line access valve caps.

VI. Conclusion

For the foregoing reasons, the Petition merely rehashes the same or substantially the same arguments recently considered by the Patent Office. The Petition fails to present new, non-cumulative art, arguments, or evidence that was not previously considered by the Office. In view of this, there is no reasonable likelihood that the Petitioner will prevail on at least one claim, and the Board should exercise its discretion and deny the Petition under 35 U.S.C. § 325(d).

Respectfully submitted,

Becton, Dickinson and Company,

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CERTIFICATE OF SERVICE

I hereby certify that, on September 16, 2014, I caused a true and correct copy of the foregoing materials:

- Patent Owner's Preliminary Response
- Exhibits 2001-2003
- Exhibit Appendix

to be served via electronic mail on the following attorney of record:

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EXHIBIT APPENDIX

Exhibit

Description

BD 2001	U.S. Patent No. 8,740,864
BD 2002	Concise Oxford English Dictionary 815 (11th ed. 2004)
BD 2003	Longman Dictionary of American English 520 (3d ed. 2004)

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

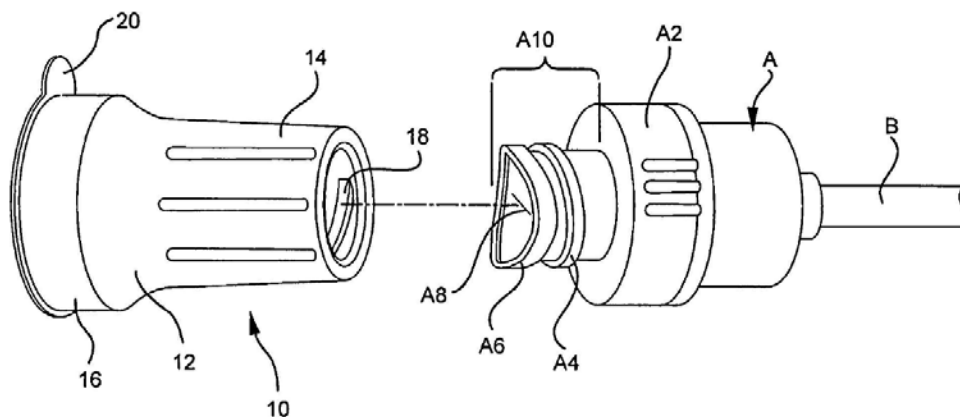


Figure 1 is an exploded view of a first embodiment of the device that includes patient fluid line access valve cap/cleaner device 10 and patient fluid line access valve A. *Id.* at 1:43–45; 1:66–2:1.

Figure 2 is reproduced below:

FIG. 2

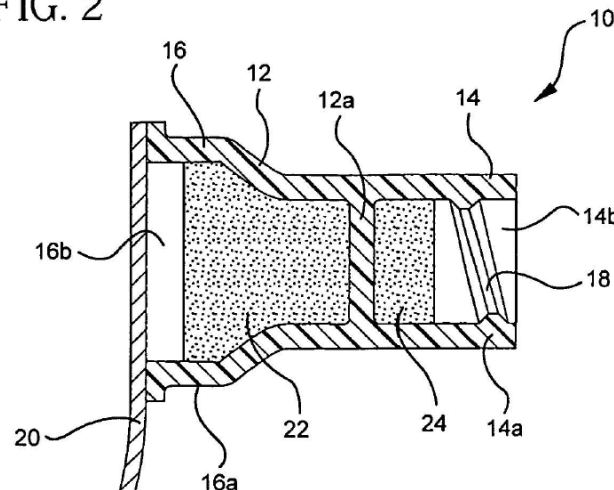


Figure 2 is a cross-sectional view of the first embodiment of cap/cleaner device 10. *Id.* at 1:46–47.

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:

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PATENT OWNER:

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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*.

SCHEDULING ORDER

A. DUE DATES

This order sets due dates for the parties to take action after institution of the proceeding. The parties may stipulate to different dates for DUE DATES 1 through 5 (earlier or later, but no later than DUE DATE 6). A notice of the stipulation, specifically identifying the changed due dates, must be promptly filed. The parties may not stipulate to an extension of DUE DATES 6 and 7.

In stipulating to different times, the parties should consider the effect of the stipulation on times to object to evidence (37 C.F.R. § 42.64(b)(1)), to supplement evidence (37 C.F.R. § 42.64(b)(2)), to conduct cross-examination (37 C.F.R. § 42.53(d)(2)), and to draft papers depending on the evidence and cross-examination testimony (*see* section B, below).

The parties are reminded that the Testimony Guidelines appended to the Office Patent Trial Practice Guide, 77 Fed.Reg. 48,756, 48,772 (Aug. 14, 2012) (Appendix D), apply to this proceeding. The Board may impose an appropriate sanction for failure to adhere to the Testimony Guidelines. 37 C.F.R. § 42.12. For example, reasonable expenses and attorneys' fees incurred by any party may be levied on a person who impedes, delays, or frustrates the fair examination of a witness.

1. INITIAL CONFERENCE CALL

The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765–66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to this Scheduling Order and any motions the parties anticipate filing during the trial.

2. DUE DATE 1

The patent owner may file—

- a. A response to the petition (37 C.F.R. § 42.120), and
- b. A motion to amend the patent (37 C.F.R. § 42.121).

The patent owner must file any such response or motion to amend by DUE DATE 1. If the patent owner elects not to file anything, the patent owner must arrange a conference call with the parties and the Board. The patent

owner is cautioned that any arguments for patentability not raised in the response will be deemed waived.

3. DUE DATE 2

The petitioner must file any reply to the patent owner's response and opposition to the motion to amend by DUE DATE 2.

4. DUE DATE 3

The patent owner must file any reply to the petitioner's opposition to patent owner's motion to amend by DUE DATE 3.

5. DUE DATE 4

a. Each party must file any motion for an observation on the cross-examination testimony of a reply witness (*see* section C, below) by DUE DATE 4.

b. Each party must file any motion to exclude evidence (37 C.F.R. § 42.64(c)) and any request for oral argument (37 C.F.R. § 42.70(a)) by DUE DATE 4.

6. DUE DATE 5

a. Each party must file any response to an observation on cross-examination testimony by DUE DATE 5.

b. Each party must file any opposition to a motion to exclude evidence by DUE DATE 5.

7. DUE DATE 6

Each party must file any reply for a motion to exclude evidence by DUE DATE 6.

8. DUE DATE 7

The oral argument (if requested by either party) is set for DUE DATE 7.

B. CROSS-EXAMINATION

Except as the parties might otherwise agree, for each due date—

1. Cross-examination begins after any supplemental evidence is due. 37 C.F.R. § 42.53(d)(2).
2. Cross-examination ends no later than a week before the filing date for any paper in which the cross-examination testimony is expected to be used. *Id.*

C. MOTION FOR OBSERVATION ON CROSS-EXAMINATION

A motion for observation on cross-examination provides the parties with a mechanism to draw the Board's attention to relevant cross-examination testimony of a reply witness because no further substantive paper is permitted after the reply. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). The observation must be a concise statement of the relevance of precisely identified testimony to a precisely identified argument or portion of an exhibit. Each observation should not exceed a single, short paragraph. The opposing party may respond to the observation. Any response must be equally concise and specific.

DUE DATE APPENDIX

INITIAL CONFERENCE CALL Dec 18, 2014 at 1:00 p.m. ET

DUE DATE 1 Feb 25, 2015

Patent owner's response to the petition

Patent owner's motion to amend the patent

DUE DATE 2 May 25, 2015

Petitioner's reply to patent owner's response to petition

Petitioner's opposition to motion to amend

DUE DATE 3 June 25, 2015

Patent owner's reply to petitioner's opposition to motion to amend

DUE DATE 4 July 16, 2015

Motion for observation regarding cross-examination of reply witness

Motion to exclude evidence

Request for oral argument

DUE DATE 5 July 30, 2015

Response to observation

Opposition to motion to exclude

DUE DATE 6 Aug 6, 2015

Reply to opposition to motion to exclude

DUE DATE 7 Aug 20, 2015

Oral argument (if requested)

IPR2014-00880
Patent 8,740,842 B2

PETITIONER:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EXCELSIOR MEDICAL CORPORATION,
Petitioner,

v.

BECTON, DICKSON 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*.

INITIAL CONFERENCE SUMMARY
Conduct of the Proceeding
37 C.F.R. § 42.5

The initial conference call for this case was held on December 18, 2014. Neither party filed a list of proposed motions. The following matters were discussed during the call.

A. Scheduling Order

Neither party expressed concerns about the schedule as set forth in the Scheduling Order.

B. Related Cases

Counsel in this proceeding were unable to provide an update on the status of the related district court litigation matters.

C. Proposed Motions

The parties indicated that settlement negotiations were ongoing and that it appeared likely that the parties may wish to move jointly to terminate these proceedings due to a settlement of the disputes among the parties. Petitioner inquired whether the parties could have authorization to file a joint motion to terminate now so that if settlement were to occur over the holidays, the parties would be pre-authorized to file such a motion. The parties also indicated that settlement had not yet occurred and that they were, therefore, not ready to move to terminate this proceeding. We therefore denied the request for pre-authorization as premature but assured the parties that we would promptly consider and rule upon such a request in the future if it were received.

D. Conclusion

In response to our inquiry, neither party expressed any other concerns or had any other questions for the panel. Accordingly, we adjourned.

IPR2014-00880
Patent 8,740,864 B2

PETITIONER:

Michael Kenaga
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PATENT OWNER:

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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*.

JOINT MOTION TO TERMINATE PROCEEDING UNDER 35 U.S.C. § 317
AND 37 C.F.R. § 42.74

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Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Pursuant to 35 U.S.C. § 317 and 37 C.F.R. § 42.74, the Petitioner Excelsior Medical Corporation (“Petitioner”) and Patent Owner Becton, Dickinson and Company (“Patent Owner”), collectively the “Parties”, hereby jointly request termination of the *inter partes* review of U.S. Patent No. 8,740,864 (“the ‘864 patent”), Case IPR2014-00880.

This *inter partes* review was recently instituted on November 25, 2014 and is therefore still in the early stages of trial. The patent owner response and motion to amend is not due until February 25, 2015. The Initial Conference Call was held December 18, 2014. The Parties advised that settlement negotiations were ongoing and that it appeared likely that the parties may wish to move jointly to terminate the proceeding. In response to the Board’s inquiry, neither Party expressed any other concerns or had any other questions for the panel. On December 31, 2014, the Parties jointly requested, and the Board granted, leave to file this Joint Motion to Terminate the Proceeding and a Joint Motion to Treat Agreement as Business Confidential.

The Parties have reached an agreement regarding their dispute relating to the ‘864 patent. The matter relating to the ‘864 patent in the District of New Jersey (*Excelsior Medical Corporation, et al v. Becton Dickinson and Company, et al*, 14-

cv-03502) was dismissed on September 22, 2014 under stipulation and prior to institution of this *inter partes* review. The matter relating to the '864 patent in the Southern District of California (*Ivera Medical Corporation and Becton, Dickinson and Company v. Excelsior Medical Corporation, Covidien LP, and Covidien Sales, LLC*, 14-cv-1348) was dismissed on December 30, 2014 under stipulation by the Parties, Ivera Medical Corporation, the Patent Owner's exclusive licensee, Covidien LP, and Covidien Sales, LLC (Exhibit No. 1038).

In accordance with 35 U.S.C. § 317(b); 37 C.F.R. § 42.74 (b), the Parties are filing a true copy of the agreement in writing as Exhibit No. 1039 with availability to the Board only. The parties are filing concurrently herewith, as a separate submission, a Joint Request to Treat Agreement as Business Confidential under 35 U.S.C. § 317(b); 37 C.F.R. § 42.74 (c). It is understood that the agreement will be designated as business confidential information and kept separate from the files of the '864 patent. It is understood that the written agreement as filed shall be available only:

1. To a Government agency on written request to the Board; or
2. To any person upon written request to the Board to make the settlement agreement available, along with the fee specified in § 42.15(d) and on a showing of good cause.

For the reasons described above, the Parties respectfully request termination of the *inter partes* review no. IPR2014-00880 of U.S. Patent No. 8,740,864.

Dated: December 31, 2014

Respectfully Submitted,
IpHorgan Ltd.

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ATTORNEYS FOR PETITIONER

**CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)**

Pursuant to 37 C.F.R. §§ 42.8(b) and 42.105(b), the undersigned certify that on the 31st day of December 2014, a complete and entire copy of this JOINT MOTION TO TERMINATE PROCEEDING and all supporting exhibits, except the agreement (Ex. 1039) which is being designated Board only, have been served electronically to the counsel of record for Patent Owner via email address:

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Wilmer Cutler Pickering Hale and Dorr LLP
David.Cavanaugh@wilmerhale.com

Heather Petruzzi
Wilmer Cutler Pickering Hale and Dorr LLP
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WEATHERLY, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

JOINT MOTION TO TREAT AGREEMENT AS BUSINESS CONFIDENTIAL
UNDER 35 U.S.C. § 317(b) AND C.F.R. § 42.74(c)

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Pursuant to the 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74 (c), the Petitioner Excelsior Medical Corporation (“Petitioner”) and Patent Owner Becton, Dickinson and Company (“Patent Owner”), collectively the “Parties”, hereby jointly request that the true copy of the written agreement referenced in the Joint Motion to Terminate Proceeding, and filed as Exhibit 1039 with availability to the Board only, be designated as business confidential information and kept separate from the files of U.S. patent No. 8,740,864 involved in this *inter partes* review.

Dated: December 31, 2014

Respectfully Submitted,
IpHorgan Ltd.

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UNDER 37 C.F.R. § 42.105(a)**

Pursuant to 37 C.F.R. §§ 42.8(b) and 42.105(b), the undersigned certify that on the 31st day of December 2014, a complete and entire copy of this JOINT MOTION TO TREAT AGREEMENT AS BUSINESS CONFIDENTIAL and all supporting exhibits, except the agreement (Ex. 1039) which is being designated Board only, have been served electronically to the counsel of record for Patent Owner via email address:

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Wilmer Cutler Pickering Hale and Dorr LLP
David.Cavanaugh@wilmerhale.com

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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.

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