

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

CASE: IPR2020-00025
U.S. PATENT NO. 9,283,367

DECLARATION OF RICHARD MEYST

I, Richard Meyst, do hereby declare and say:

1. I am over the age of twenty-one (21) and competent to make this declaration.
I am also qualified to give testimony under oath. The facts and opinions listed below are within my personal knowledge.
2. I am being compensated for my time in this proceeding at my standard consulting rate of \$475/hr. My compensation in no way depends on the outcome of this proceeding or the content of my opinions. I am not employed by, nor receiving grant support from the Petitioner in this matter. I am receiving compensation from Petitioner solely for my involvement in this matter and based only on my standard hourly consulting fees.
3. I have been asked to review certain documents, including U.S. Patent No. 9,283,367 (the “367 Patent”) (Ex. 1001) and to provide my opinions on how those of skill in the art (as defined herein) would understand those documents. The documents I was asked to review include those addressed in more detail in the rest of this declaration. I provide my conclusions regarding the disclosures of these documents below.
4. Of particular relevance to the ‘367 Patent, I have reviewed and am familiar with the following documents:
 - a. U.S. Patent No. 4,440,207 to Genatempo et al. (“*Genatempo*”) (Ex. 1006);

- b. U.S. Patent No. 5,554,135 to Menyhay (“*Menyhay*”) (Ex. 1007);
- c. U.S. Patent Publication No. 2005/0013836 to Raad (“*Raad*”) (Ex. 1016);
- d. U.S. Patent Publication No. 2004/0111078 to Miyahara (“*Miyahara*”) (Ex. 1009);
- e. U.S. Patent Publication No. 2003/0153865 to Connell et al. (“*Connell*”) (Ex. 1010);
- f. U.S. Patent Publication No. 2006/0030827 to Raulerson et al. (“*Raulerson*”) (Ex. 1011);
- g. U.S. Patent No. 6,475,434 to Darouiche (“*Darouiche*”) (Ex. 1015); and
- h. Needleless connectors-the way forward in the prevention of catheter-related infections, A.L. Casey et al., Journal of Hospital Infection, 77-81 (2002) (Ex. 1017).

I have also reviewed the Petition and institution decision in IPR2014-00880. (Ex. 1005). I understand that the proceeding in IPR2014-00880 was instituted but never reached final written decision. To the extent not explicitly mentioned above, I have also reviewed any additional documents cited in this declaration.

5. I was asked to provide my opinion on the technical feasibility of and the basis for combining certain aspects of certain documents. I have offered my opinion on these issues in this declaration.
6. I am not offering any conclusions as to the ultimate determinations of obviousness or patentability, as I understand the Board will make in this proceeding. I am simply providing my opinion on the technical aspects of the documents (including, where asked, the application of what I understand Petitioner asserts is the appropriate construction for this proceeding) and on the reasons for combination and modification of any disclosures as well as what those combinations and modifications would result in from a technical perspective.

BACKGROUND

7. My qualifications and listing of publications are detailed in my *curriculum vitae*, which is attached as Exhibit 1004 and includes, among other things, my academic credentials and my employment history. This includes a list of issued patents and publications on which I am a named inventor in the previous 10 years and a list of all other cases in which I have testified as an expert at trial or by deposition in the previous 4 years. I am currently the President and Chief Executive Officer of Fallbrook Engineering, Inc. I am an

engineer and consultant in the field of medical devices and related technologies, including cardiovascular catheters.

8. I received a M.S. (1972) and B.S. (1971) in mechanical engineering from the University of Wisconsin, Madison. My undergraduate academic work focused on design, manufacturing methods, fluid mechanics, and heat transfer. My graduate academic focus was on computer-based automatic controls of systems and my Master's thesis was on concept development, design, fabrication, and testing of a prototype bench-top implantable mechanical human heart. Additionally, I have participated in industry seminars and training programs covering design of experiments, statistical analysis, biocompatibility testing, sterilization method selection and validation, design of plastic parts, design for manufacturability, package design and testing, cellular therapy, and many others.
9. As an engineer, designer, consultant, program manager and entrepreneur at Fallbrook Engineering, Inc., I have been involved in the advanced design and development of a wide range of medical technology products for the healthcare industry for more than 40 years. Prior to 1989 when I became a partner in Fallbrook Engineering, I held various leadership positions at technology and product development companies. From 1972 to 1974, I worked for United States Catheter and Instrument Corporation, a division of

C.R. Bard, Inc. I was a product engineer supporting Vascular Graft and Cardiovascular Catheter product lines. As part of my work there, I designed, implemented, and evaluated specialty test equipment and testing procedures. I also implemented a program to quantify and control variables affecting product quality. The work included development of multi-lumen profile extrusions for use in diagnostic and therapeutic catheters

10. From 1974 to 1979 I worked for the Fenwal Division of Baxter Travenol Labs, starting out as a senior engineer and ultimately being promoted to a program manager. During that time, I was involved in the design and management of human blood component products, including sterile medical disposables and electronic, electro-mechanical biomedical hardware used in Cellular Therapy.
11. From 1983 to 1988, I worked for Imed Corp. as a manager of various design, engineering and manufacturing groups. During this time, I managed the design, development and manufacturing of a number of IV infusion pumps, enteral feeding pumps, and associated sterile medical disposables product lines.
12. From 1988 to 1989, I worked for Diatek Corp. as a manager of Manufacturing Engineering. During this time, in addition to supporting the company's manufacturing activities, I was involved in inventing a probe cover and

package disposable for a next generation tympanic electronic hospital thermometer.

13. Since 1989, I have been a partner and owner at Fallbrook Engineering. From 1989 to 2003, I was a Vice President, and since 2003, I have been the President and Chief Executive Officer. During my time at Fallbrook Engineering, I have been involved in providing consulting services in the medical, pharmaceutical, biotech, electronic, and consumer product industries. The consulting services include project management, product conception, design and development, product prototyping, design and process validation, manufacturing engineering, production startup, cost reduction, as well as regulatory affairs compliance and regulatory submissions.
14. Over the years, I have had a consistent focus on medical devices and related technologies which utilize my particular expertise in inventing, product design and manufacturing methods design, fluid mechanics, drug delivery, cellular therapy, high volume sterile disposables and FDA regulatory matters.
15. My medical product experience includes, but is not limited to, product and packaging design, the development of implantable vascular prostheses, DNA amplifiers, vital signs monitoring devices, IV drug infusion pumps and administration sets, over the needle IV catheters, self-injection training devices, cardiac catheters, various balloon catheters, introducer sheaths,

diagnostic catheters, special purpose syringes, safety syringes, diagnostic and therapeutic medical lasers and optical catheters, surgical instruments, microprocessor based diagnostic and therapeutic instruments, blood cell collection, separation, processing, and administration devices, filtration devices for blood and intravenous solutions, stem-cell harvesting and cell expansion systems.

16. I have been a Principal Investigator on a National Institute of Health Small Business Innovation Research (“SBIR”) grant from the National Heart, Lung and Blood Institute developing a device for the improved collection of umbilical cord blood stem cells. This product was designed to safely collect cord blood without exposed sharps and in a shielded state to prevent blood spatter. I served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and am a long-time member. I am a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation, and the American Filtration Society. I have also been a long-time member of the Medical Device Steering Committee of BIOCOM, the largest, most experienced leader and advocate for California’s life science sector representing over 750 biotechnology, pharmaceutical, digital health and medical device/diagnostic companies. I have been a judge in the San Diego CONNECT capital competition for startup

companies. On several occasions I have been a juror in the UBM/Cannon Medical Design Excellence Awards competition (“MDEA”). This annual competition is the premier design awards program for the medical device industry.

17. I also have been an invited speaker, presenting technical and business talks at numerous scientific and medical industry meetings and have authored articles published in trade magazines.
18. For these reasons and because of my technical experience and training as outlined in my *curriculum vitae* (Ex. 1004), I believe I am qualified to offer technical opinions regarding the ‘367 Patent and the other documents I reviewed as part of my work in this matter. I believe I am capable of opining about the state of the art in these areas at various points in time from the mid-2000s to the present, as I have been familiar with the academic understanding of medical devices, as well as the design considerations that are to be accounted for in medical devices.

TECHNOLOGY OVERVIEW

Brief History of Patient Fluid Lines

19. Sterile disposable tubing fluid lines have been used for numerous healthcare treatment purposes for many years. These tubes allow for conveying fluids to or from a patient and are often connected to indwelling cardiovascular devices

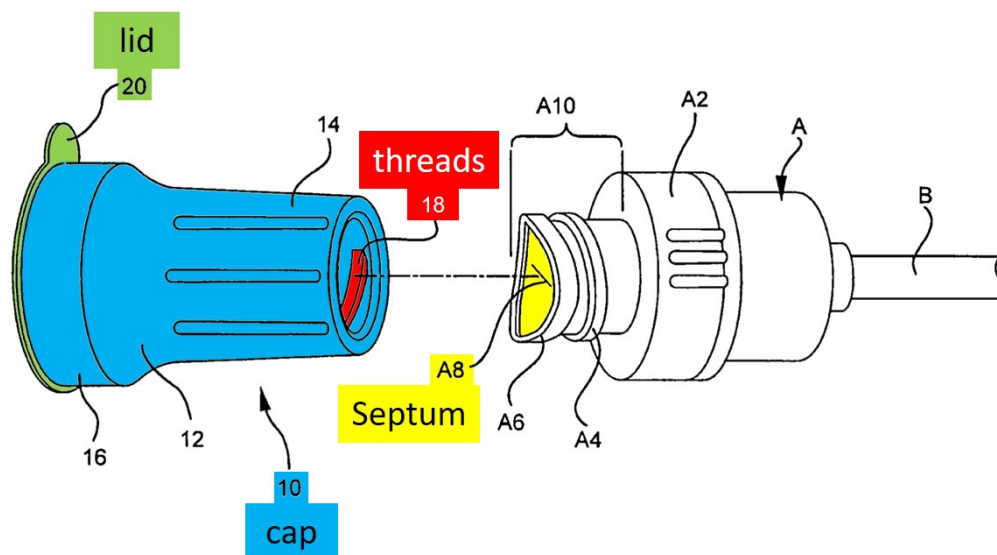
such as hemodialysis and peritoneal catheters, central venous line catheters, urine drainage catheters placed into the patient's bladder and many other devices. Patient fluid lines are single use devices that are packaged and sterilized. Aseptic technique is used to place these devices in the patient, or to connect to these lines, as any microbial contamination can lead to the patient becoming infected and even the development of life-threatening peritonitis or sepsis.

20. Access to these fluid lines previously was done by using a sterile needle on a syringe or tubing set to penetrate a rubber stopper which was a part of the disposable tube set. The rubber stopper and other connection components were prepped with an antiseptic solution to minimize the chance of microbial contamination. However, the use of needles led to accidental needle sticks of healthcare workers, raising the risk of infection. To prevent accidental needle sticks, needless connectors of various designs were developed and sold in the early 1990s. While this new type of connector eliminated needle sticks, they were sometimes hard to clean and disinfect prior to use which led to patient contamination and infections. As demonstrated above and herein, by 2005, it was well-known in the industry to use anti-microbials to clean patient tubing connections, and that such cleaning dramatically reduced the risk of infections.

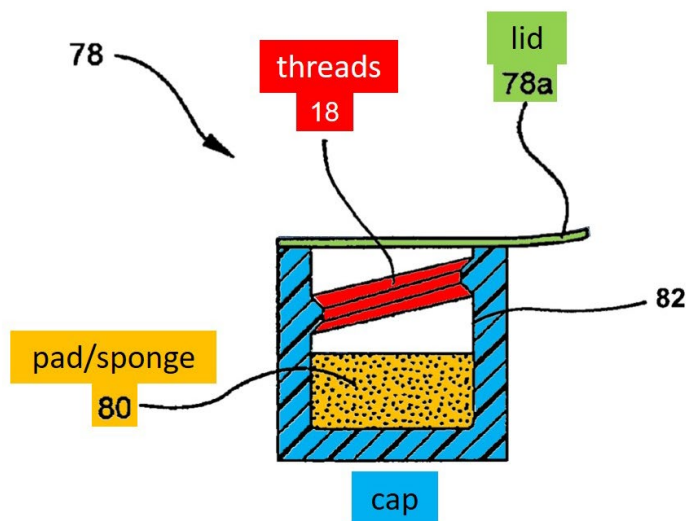
U.S. PATENT NO. 9,283,367

21. The '367 Patent is titled "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner." The '367 Patent issued from an application filed on January 21, 2014, and claims priority to U.S. Application No. 11/281,711 ("the '711 Application") filed on November 17, 2005. (Ex. 1001, Cover). The '711 Application issued as U.S. Patent No. 8,740,864 ("the '864 Patent").
22. The '367 Patent is generally directed to a device for antiseptically cleaning and maintaining what it refers to as a "patient fluid line access valve" or a patient tube such as a catheter. (Ex. 1001, 1:49-50). The '367 Patent accomplishes this by providing a cap/cleaning device 10 which threadingly attaches to the patient line access valve A (as shown in Fig. 1 reproduced below). (Ex. 1001, 1:59-61; 2:15-18, Fig 1).

FIG. 1



23. The '367 Patent relies upon a threading engagement between the cap and the line to advance the face of the line (A8 above) into the interior of the cap 10. The '367 Patent further shows that cleaning end 16 is covered by lid 20 which may be removed to expose wet pad 22. (Ex. 1001, 2:34–35, 39–43; Fig. 2). The cap of the '367 Patent may be made of any number of known plastic materials. (Ex. 1001, 2:28-32). The use of these plastics was well known in the medical device field. Another illustration of the claimed mechanical cap is depicted below in annotated figure 10b, showing lid 78a in green, threading 18 in red, sponge 80 in orange, and cap 78 in blue.



24. During treatment of a patient, the patient fluid line described by the '367 Patent (e.g., a catheter) is left in the patient's body while an access valve remains external to the body, accessible by the patient, by medical professionals, and to the environment. In this access valve, there is a septum

into which a male luer may be inserted to administer fluids to the patient or withdraw fluids from the patient. The disinfecting cap of the '367 Patent is threadingly attached to the access valve when the patient is not being treated, protecting the face and inhibiting bacterial contamination of the patient's access valve. This patient line disinfecting cap is, at its essence, a threaded cap with an antiseptic-soaked sponge within the cap.

25. I understand that the '864 Patent was previously challenged at the Patent Office. (Ex. 1005). I have been asked to apply the claim constructions of "external threads on the access portion proximate the septum" and "length" that the board preliminarily adopted and the construction of "access portion" that the Patent Owner proposed in the earlier proceeding. These claim constructions are as follows:

Term	Construction
"external threads on the access portion proximate the septum"	This term requires the external threads to be located on the access portion very near the end face as compared to other parts of the access portion.
"length"	"Length" refers to a measurement from one end of a thread to the other end of that thread.
"access portion"	This term refers to the exposed surface of the septum and the exposed surface of the housing that surrounds the septum.

LEVEL OF SKILL IN THE ART

26. I was asked to provide my opinion about the experience and background a person of ordinary skill in the art (“POSA”) of the ‘367 Patent would have had as of November 17, 2005.
27. With respect to the ‘367 Patent, a POSA as of November 17, 2005 would have had an undergraduate degree or equivalent thereof in mechanical engineering or biomedical engineering with at least three years of experience in product design with experience in, for example, catheters, medical ports, and other patient fluid line access valve caps. Additional graduate education might substitute for experience and vice-versa. A POSA would have had knowledge of design considerations known in the industry and would have been familiar with then existing products and solutions, and would have understood how to search available literature for relevant publications.
28. I believe that based on my experiences outlined above, I can opine today about what those of skill in the art would have known and understood as of November 17, 2005.

OVERVIEW OF THE PRIOR ART REFERENCES

Menyhay

29. As part of my work in this proceeding, I was asked to review U.S. Patent No. 5,554,135 to Menyhay (“*Menyhay*”) (Ex. 1007). *Menyhay* describes a sterile

medical injection port and cover method and apparatus consisting of an external port cover that is open on one end and closed on the other end. (Ex. 1007, Abstract).

30. The interior of the cover is configured with a set of spiraling screw threads which mate with corresponding screw threads located on the exterior surface of an external medical fluid injection port. (Ex. 1007, Abstract, 4:10-12, 4:19-21). Within the cover, there is a closed frangible breakable plastic vessel containing a combination of liquid antiseptic, bactericidal and virucidal agents. (Ex. 1007, Abstract, 4:13-15). A porous sponge is located proximal to the liquid container. (Ex. 1007, Abstract, 4:17-18). As the port cover is screwed into place over the injection port, it first creates a sealed chamber (Ex. 1007, 4:22-24) and then an inwardly projecting point of the cover comes into contact with the frangible container and causes the container to rupture, dispensing the contents of the container (the various antiseptic, bactericidal, and virucidal solutions) into the interior of the port cover which are then soaked up by the sponge. (Ex. 1007, Abstract, 4:24-27). As tightening continues, the antiseptically treated sponge contacts the latex membrane of the port, bathing it with the liquid soaked up by the sponge, cleaning the face of the port. (Ex. 1007, Abstract, 4:27-30). The assembly within the cover stays bathed in antiseptic until the cover is removed and discarded when the



31. *Menyhay* states that the cap or cover may be a cylinder that is open on one end and includes screw threads 15 on the inside. (Ex. 1007, 6:38-40, Fig. 2). A rubberized O-ring 14 is provided proximal to the open end of cylinder 10. (Ex. 1007, 6:41-43, Fig. 2). The frangible liquid containing capsule 11 is located inside cylinder 10 near sponge 12. Capsule 11 is filled with povidone iodine and isopropyl alcohol (a known antiseptic, bactericidal and virucidal solution). (Ex. 1007, 6:44-49, Fig. 2). External liquid injection port 19 has septum 18 made of resealable rubber material. (Ex. 1007, 6:53-58, Fig. 2). Screw threads 17 are on the exterior of port 19 which mate with screw threads

15 on the interior of cover 10 so that port 19 may be screwed into cover 10 (like a bolt into a nut). (Ex. 1007, 6:53-58, Fig. 2).

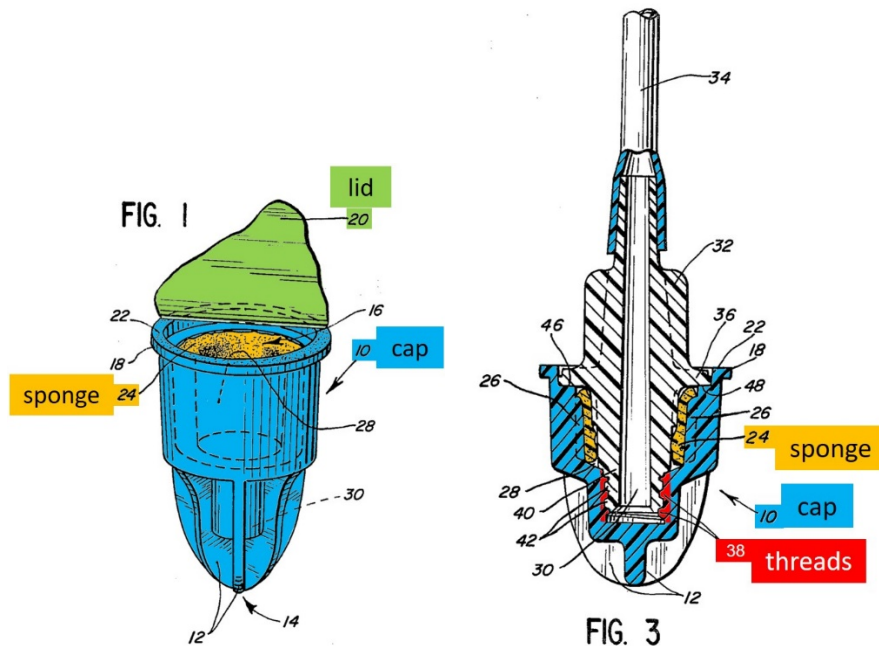
32. As the cap 10 is screwed over the port 19 the O-ring creates a seal on the open end of the cap to create a liquid tight enclosure that will ultimately contain the antiseptic solution. (Ex. 1007, 6:59-61). Further tightening of the threads ruptures the container 11 holding the antiseptic solution, which is then soaked up by the sponge 12. (Ex. 1007, 6:61-66, Fig. 2). Since the wet sponge is in direct contact with the port (due to the threading advancement of the port into the cap), antiseptic liquid flows to the rubber membrane and bathes the port in an antiseptic, bactericidal and virucidal solution. (Ex. 1007, 6:67-7:3). The port cover needs no maintenance while applied which results in a decreased risk of contamination and infection and longer life of the injection port itself. (Ex. 1007, Abstract). *Menyhay* also states, “[t]he present invention can be used not only to cover but also to aseptically cleanse the surface of an injection port simply by being firmly attached thereto.” (Ex. 1007, 7:4-6).

Genatempo

33. As part of my work in this proceeding, I was asked to review U.S. Patent No. 4,440,207 to Genatempo et al. (“*Genatempo*”) (Ex. 1006).
34. *Genatempo* describes an antibacterial/antimicrobial cap for providing a non-contaminated environment to house a patient connection valve, medical port

opening or connector, such as those used in peritoneal dialysis. (Ex. 1006, Abstract, 1:6-14, 1:64-67, claim 1, claim 7). *Genatempo*'s cap can also be used with other medical connectors which would benefit from an antiseptic engagement. (Ex. 1006, 2:4-7, 2:19-20). The cap creates a desirous environment in the interior of the cap and around the exterior of the connector by incorporating a liquid antiseptic into an absorbent material which lines a portion of interior of the cap and which comes into direct contact with the connector. (Ex. 1006, 1:59-2:15, Abstract, claim 11).

35. A secure liquid tight connection of the cap to the connector is achieved by the use of a threaded engagement of complementary threaded portions on the inside surface of the cap and on the outside surface of the connector. (Ex. 1006, 2:21-27, claim 3). Additionally, certain features may be added to the cap cavity to prevent over advancement of the connector into the cap, potentially reducing the risk of damaging the threads. (Ex. 1007, 3:47-51). The connector exterior and threaded portions are coated by the liquid antiseptic when connected through (1) direct contact with the liquid infused absorbent, (2) by migration of the liquid from the absorbent materials to the exterior surfaces of the connector, or (3) by both methods. (Ex. 1006, 1:59-63, 3:40-45).



36. The antiseptic solution of *Genatempo* is pre-positioned within the cap where it is impregnated into the absorbent material. (Ex. 1006, 2:36-38). The protective cap interior is secured and isolated from the outside environment through the sealing of the cap cavity by a removable, peelable water vapor barrier lid. (Ex. 1006, 2:63-66, 3:1-3). This lid ensures an acceptable shelf life by keeping the volatile antiseptic solution, such as povidone iodine, from evaporating and further ensures external contaminants do not interfere with the solution. (Ex. 1006, 3:1-5). The cap housing is made from a non-porous thermoplastic which may be injection moldable. (Ex. 1006, 3:19-22, claim 10). The cap may be configured to include interior ribs which can be welded to the absorbent material. (Ex. 1006, 3:16-19, claim 2). Additionally, the cap may include exterior gripping fins to allow the user to securely hold the device

while assembling the cap to the valve/connector. (Ex. 1006, 2:58-61). The absorbent material may be a plastic made of a polyether-based polyurethane material or similar material, known plastics suitable for manufacture in the medical device field. (Ex. 1006, claim 8).

Raad

37. As part of my work in this proceeding, I was asked to review U.S. Patent Publication No. 2005/00013836 to Raad (“*Raad*”) (Ex. 1016).
38. *Raad* states that it discloses a way of reducing microbial organisms from indwelling medical devices (like dialysis catheters), medical equipment and other surfaces. (Ex. 1016, ¶3). *Raad* discloses the use of solutions that comprise alcohol and an antimicrobial agent in accomplishing this goal. (Ex. 1016, Abstract). *Raad* further discloses “methods for reducing microbial organisms from a surface comprising: a) obtaining an antimicrobial solution of the invention as set forth above; and b) contacting the surface with the antimicrobial solution, whereby said contacting reduces microbial organisms from the surface.” (Ex. 1016, ¶39). Contact time can be as little as 15 minutes or less and up to 4 hours or less. (Ex. 1016, ¶40).
39. The solution of *Raad* may be applied to a surface, “wherein the surface is the surface of a medical device, indwelling catheter, organic surface or inorganic surface.” (Ex. 1016, claim 26). Additionally, *Raad* discloses many uses of

its solution, including cleaning of a generic catheter, a hemodialysis catheter, a urinary catheter, and a peritoneal catheter, all of which are specific devices which may rely upon a needleless connector cap. Numerous other types of surfaces encountered in a healthcare setting are also listed. (Ex. 1016, claim 27).

Miyahara

40. As part of my work in this proceeding, I was asked to review U.S. Patent Publication No. 2004/0111078 to Miyahara (“*Miyahara*”) (Ex. 1009).
41. *Miyahara* describes a medical fluids connector system for making sterile connections. (Ex. 1009, Cover). *Miyahara* discloses a male type connector having a tube connecting portion at a rear end. (Ex. 1009, ¶36). Further, the system includes a female type connector that mates with the male type connector. (Ex. 1009, ¶36). *Miyahara* also discloses a protective cap for the patient side connector (a connector that is on a tubing connected to a catheter that is placed in the patient for up to a half year). (Ex. 1009, ¶36, Abstract). When used in a peritoneal dialysis system the male type connector may be on the patient side and the female connector is on the side connected to the dialysis circuit. (Ex. 1009, ¶¶12-13)
42. The protective cap has a substantially cylindrical shape with a closed first end. (Ex. 1009, ¶¶12-13). The cap is capable of connecting and disconnecting

with/from a male type connector. (Ex. 1009, ¶¶12-13). Within this protective cap is an inner cap 3 that includes a ring-shaped element that supports a sponge like disinfectant-impregnated member that participates in ensuring the system makes sterile connections. (Ex. 1009, ¶¶12-13, 35). The disinfectant can be Isodine (brand name of povidone-iodine) or a similar bactericidal solution. (Ex. 1009, ¶42).

43. During use of the system described by *Miyahara*, inner cap 3 with the disinfectant is automatically transferred from the male connector to the female connector at appropriate times to place the disinfectant at the most strategic location to provide a sterile connection. (Ex. 1009, ¶¶36-37). The design of the system also allows for a new fresh disinfectant inner cap to be automatically added whenever a new connection is made or broken. (Ex. 1009, ¶¶13).
44. The mechanical interface between the male and female connector includes numerous features that, when combined with manual insertion and rotation of the connectors, automate the transfer of the inner cap from location to location. (Ex. 1009, ¶¶55-57). Molded-in guide grooves and guide protrusions, snap fits, channels, blocking surfaces combined with user actions such as axial motions and component rotations cause the guide protrusion to slide along the guide groove 13, “so that the male type connector is pulled into

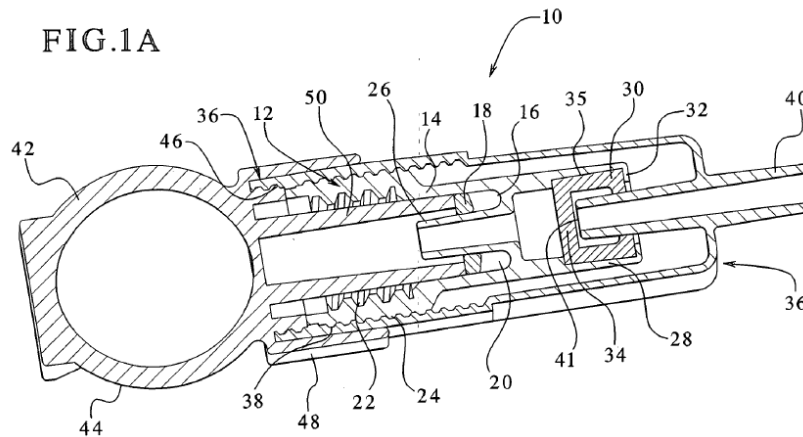
an inside of the protective cap by a driving force resulting from a screw action by the inclined portion of the guide groove....” (Ex. 1009, ¶¶16). When this occurs, blocking features limit further rotation “of the male type connector, so that a force in the axis direction acts on the inner cap so as to separate the inner cap from the male type connector, resulting in the release of the engagement between the inner cap and the male type connector, and the inner cap assumes a state of being retained by the inner cap retaining portion of the outer cylinder.” (Ex. 1009, ¶¶17).

Connell

45. As part of my work in this proceeding, I was asked to review U.S. Patent Publication No. 2003/0153865 to Connell et al. (“*Connell*”) (Ex. 1010).
46. *Connell* describes a connector and a cap incorporating a disinfectant for medical connections, such as in Peritoneal Dialysis (PD), that need to be performed in a sterile or aseptic fashion. (Ex. 1010, ¶¶14-15, Fig. 2). *Connell’s* system can also be used with infusion therapy, or any medical fluid transfer activity that needs to be germ free. The disinfectant is contained within the cap such that it is safe and easy for the patient to use. (Ex. 1010, ¶¶66). *Connell* includes a cap 12 and a connector 10 that may be made of medical grade plastics. (Ex. 1010, ¶¶14-15, 68, Fig. 2).

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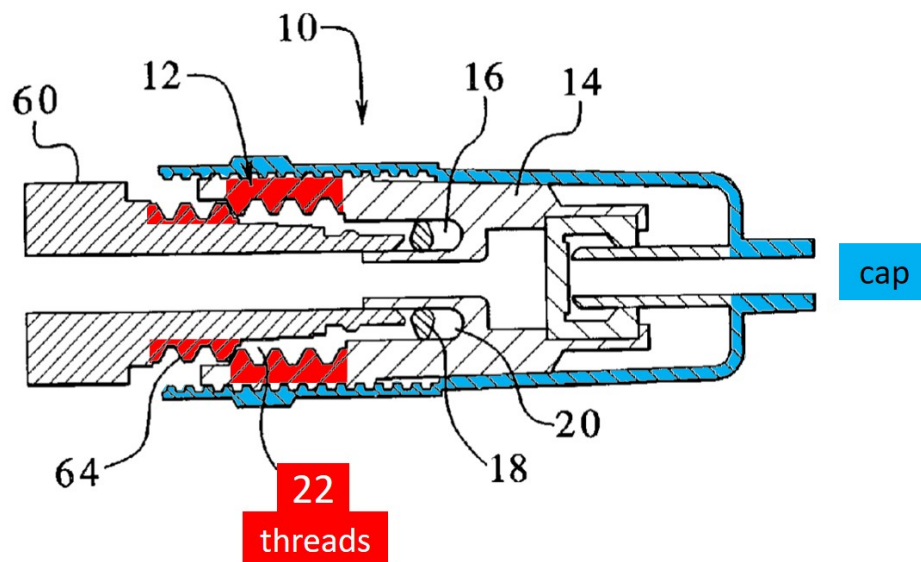


48. Seal 18 may be secured in place by an adhesive or by heat sealing in place. (Ex. 1010, ¶74). An alternative seal consists of a thin puncturable/frangible film 18 that is sealed about the cavity 16 to contain the liquid antiseptic. (Ex. 1010, ¶74). This membrane/film is torn or otherwise breached by actions taken by the patient when using the device (e.g., screwing the pieces together as set forth below), releasing the disinfectant to flow to other portions of the cap. (Ex. 1010, ¶74).
49. The disinfectant of *Connell* can be any type of solution capable of substantially sterilizing upon direct contact the plastic, rubber or metal components. (Ex. 1010, ¶76). One such disinfectant is povidone iodine; other suitable alternatives include iodine-containing antimicrobials and betadine (i.e., the brand name of povidone-iodine), and may include any disinfectant know to a POSA. (Ex. 1010, ¶76). In some cases, these materials may be sterilized by irradiation, autoclave or ethylene oxide gas. (Ex. 1010, ¶76).

50. Internal and external threads allow two separate members of the invention to move along the central axis of the body 14 inward and outward relative to the body 14 of cap 12. (Ex. 1010, ¶77). Various thread geometries are employed to control and limit relative motion. (Ex. 1010, ¶78).
51. A tip protector 42 that covers body 14 and shell 36 is applied at the factory and serves multiple functions. (Ex. 1010, ¶78, Fig. 2). It acts as a microbial barrier keeping bacteria and other harmful airborne contaminants from coming into the body 14 of the cap 10 prior to use. (Ex. 1010, ¶¶87-88, Fig. 2). The tip protector 42 also incorporates a handle that the user/patient grabs to remove and discard the protector just prior to use. (Ex. 1010, ¶¶87-88, Fig. 2).
52. The protector also establishes the relative position of various components for packaging, shipping and handling. (Ex. 1010, ¶89). Further, the tip protector 42 prevents accidental release of the antiseptic solution by protecting seal 18 from movement or rupture. (Ex. 1010, ¶95, Fig. 2). The tip protector 42 enables handling and shipping of the connector 10 “without destroying the seal 18 and/or losing the disinfectant 20 maintained by the seal 18.” (Ex. 1010, ¶95, Fig. 2).
53. A substantially sterile connection is possible once the tip protector 42 is removed and discarded. Transfer set 60 is connected to connector 10 and as

it engages the internal threads and is rotated, ends 66 of the transfer set translate inward and come in contact with seal 18. (Ex. 1010, ¶101, Fig. 4). As 60 progresses it either moves or ruptures seal 18 causing disinfectant 20 to leave receptacle 16 and squirt out around seal 18 and ends 66. (Ex. 1010, ¶101, Fig. 4). Then disinfectant 20 is caused to “run out over the external threads of connector 60, so that microorganisms contained thereon are substantially destroyed.” (Ex. 1010, ¶102). As connector 60 slides along the passage 26 of body 14 it disperses “the disinfectant 20 onto the outside of the mating connector 60 to disinfect the engaging threads.” (Ex. 1010, ¶103). “That is, the disinfectant will take the path of least resistance and tend to move into the open cavity defined between the outside of the connector 60 and an inner wall of the body 14, rather than squeezing through the friction fit between the inner opening of the connector 60 and the passage 26.” (Ex. 1010, ¶103).

FIG.4



54. Once the sterile connection has been accomplished, additional rotations of the elements causes shell 36 to move towards connector 60 which causes port 40 of the shell 36 to pierce split septum 30 opening fluid communication between the patient's peritoneal cavity and the dialysate bag. (Ex. 1010, ¶104). Once the exchange of dialysate has been completed, tube 40 is removed from the slit septum, which closes of its own accord. (Ex. 1010, ¶108). "The body 14 remains in the threaded position with respect to the mating connector 60, so that the disinfectant 20 is maintained between the mating threads and the open area between the mating connector 60 and the body 14." (Ex. 1010, ¶108).

Raulerson

55. As part of my work in this proceeding, I was asked to review U.S. Patent Publication No. 2006/0030827 to Raulerson et al. ("*Raulerson*") (Ex. 1011)

56. *Raulerson* describes a device for cleaning medical luer connectors. (Ex. 1011, Abstract). *Raulerson* is generally directed towards a hollow cylindrical device which is closed on one end and open on the other. (Ex. 1011, Abstract). The device first end 104 is an open end containing a plurality of bristles 134 extended from the inside surface towards the device's longitudinal axis. (Ex. 1011, Abstract, Fig. 3). The bristles are sufficiently long to contact a luer's surface when it is inserted into the open end. (Ex. 1011, Abstract). This open brush end with bristles is sized to receive and accommodate the proximal end of a standard medical luer connector. (Ex. 1011, Abstract; Fig. 2). The closed second end 164 is part of a compressible reservoir containing a fluid 168. (Ex. 1011, Abstract, Fig. 2). The fluid is a fluid having antiseptic properties, such as isopropyl alcohol, povidone iodine or hydrogen peroxide. (Ex. 1011, ¶29). When the second end is compressed, the fluid is transmitted from the reservoir toward the first end through passageways where it wets the bristles and the luer's proximal end. (Ex. 1011, Abstract).

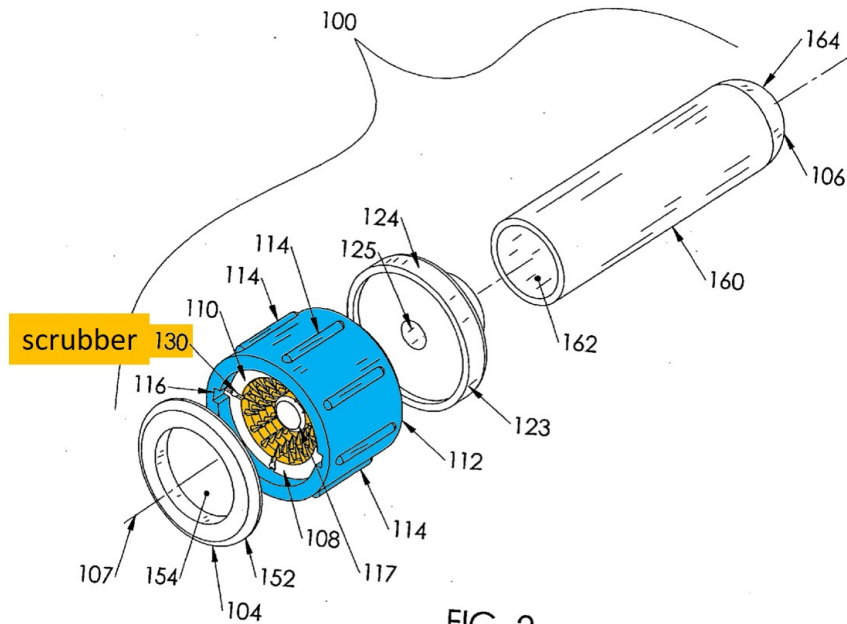


FIG. 2

57. To clean and disinfect the proximal end and threads of a luer inserted into the open end 104 of cleaner 100, the closed end containing the disinfectant is squeezed forcing antiseptic fluid to the first end where it wets the bristles and the luer. (Ex. 1011, ¶4). Luer cleaner 100 may be inserted over a luer connector 190 and rotated axially around the luer. (Ex. 1011, ¶14, Fig. 1). Additional cleaner can be expressed into first end 104 at any time during the scrubbing process. (Ex. 1011, ¶4). This wet scrubbing loosens debris while the fluid washes, cleans and decontaminates the luer connector end. (Ex. 1011, ¶4).

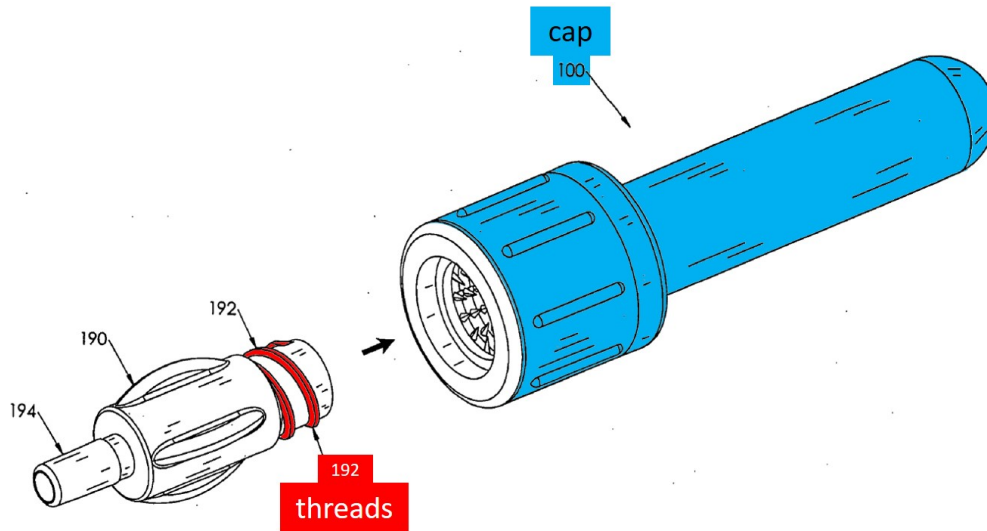


FIG. 1

58. A POSA would understand that the combination of liquid antiseptic and scrubbing with bristles is a more aggressive cleaning and disinfecting process than merely contacting luer surfaces to antiseptic solutions. As the luer may be used with critical connections such as those associated with hemodialysis catheters, efficient and complete cleaning and disinfection is essential.

Scholz

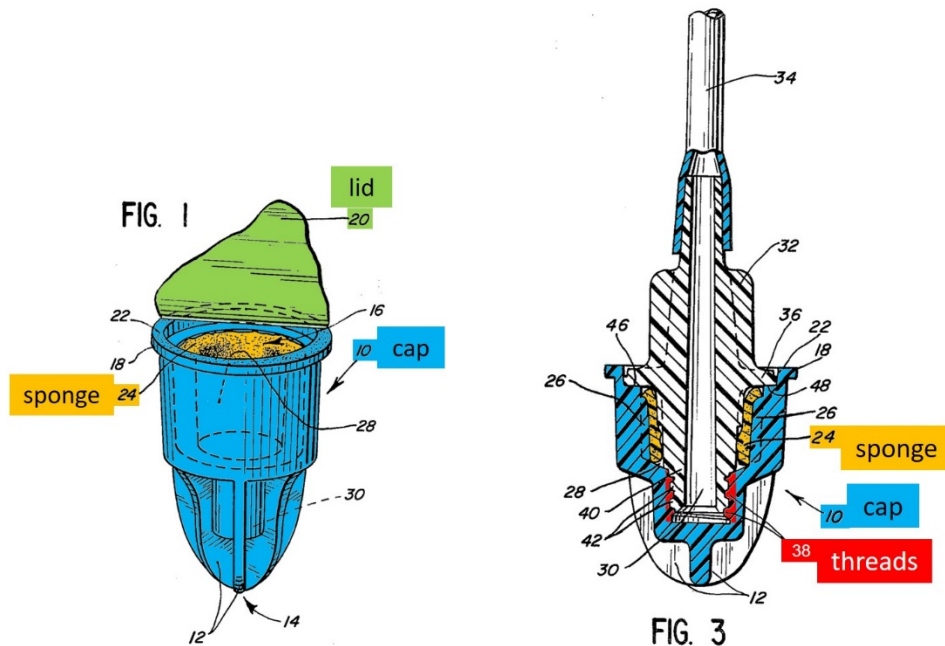
59. As part of my work in this proceeding, I was asked to review U.S. Patent No. 9,028,582 to Scholz (“*Scholz*”) (Ex. 1012).

60. *Scholz* discloses a variety of then-existing antiseptics “chlorhexidine and its various salts including...diacetate” as well as gluconate as an improvement over povidone-iodine. (Ex. 1012, 3:55-67, 15:35-41). Further, *Scholz* discloses that the compositions “can be coated onto medical devices that contact skin, mucus membranes, wounds, etc. Examples of such devices

include catheters.” (Ex. 1012, 47:66-48:2). *Scholz* confirms the use of chlorhexidine salts as a disinfectant for medical devices.

SUMMARY OF OPINIONS

61. As discussed in more detail below, my review of prior art documents in this proceeding demonstrates that, in general, the concepts of the ‘367 Patent were not new as of November 17, 2005.
62. My review of the documents referenced in the preceding section comports with my experience that those of skill in the art prior to November 2005 knew of then-existing patient tube contamination issues as well as the myriad solutions available at the time, including the use of a cap containing an antiseptic impregnated sponge that cleaned the external surfaces of the line tube connector.
63. For example, *Genatempo* describes a cap and connector assembly where an antiseptically impregnated sponge is used to clean and protect connector 32. (Ex. 1006, 3:43-45).



(Ex. 1006, Figs. 1 and 3). When combined with *Menyhay's* cleaning of a septum located at the end of a patient tube (Ex. 1007, 6:40-7:3), a POSA would understand that the resulting combination would include a pre-impregnated sponge that provides an antiseptic solution to the threads and face (septum) of the connector.

64. In another example, *Connell's* disclosure of a fluid connector cleaner that cleans the threading of a connector (Ex. 1010, ¶¶100-103) confirms that cleaning caps that thread onto a connector end were well known to a POSA as of 2005. *Raulerson's* disclosure of brushes confirms that an abrasive surface provides additional cleaning benefits over merely bathing a surface in antiseptic solution. (Ex. 1004, ¶4).

65. *Genatempo* confirms that one manner of providing a cleaning solution within a fluid connector cleaner is via a sealed cap that includes an antiseptically impregnated sponge. (Ex. 1006, Abstract, 2:62-68, 3:34-35).
66. *Raad* may be combined with the aforementioned combinations to clarify that the antiseptic solution would include a combination of alcohol and chlorhexidine gluconate, a known effective antimicrobial cleanser for medical devices. (Ex. 1016, Abstract, ¶28). *Raad* further confirms that povidone iodine and chlorhexidine gluconate are suitable replacements for antiseptic solutions in the field of indwelling medical devices. (Ex. 1016, ¶¶28, 78-79).
67. *Miyahara* discloses that a cleaning and protective cap may be securely adhered to a connector with a rotation that is less than one full rotation of the cap, confirming that the threading in the aforementioned combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶55-56, Fig. 3).
68. These references recognize the use of antiseptic solutions in connector cleaner caps, where the cap is threaded onto the connector. Further, the references confirm the use of pre-wetted sponges to store and dispense the antiseptic cleaner, as well as to assist in the cleaning process.
69. Moreover, the combinations I was asked to consider, as set forth below, (*i.e.*, *Mehyhay* and *Genatempo*; *Menyhay*, *Genatempo*, and *Raad*; *Menyhay*,

Genatempo, and Miyahara; Connell, Raulerson, and Genatempo; Connell, Raulerson, Genatempo, and Raad; and Connell, Raulerson, Genatempo and Miyahara) could and would have been made by a person of ordinary skill in the art as of November 17, 2005.

COMBINATIONS

Basis for a Modification

70. I have been told that combinations of the prior art should be analyzed based on the mindset of one of skill in the art at the time the invention was made. Counsel has advised me that in rendering my opinions, I should cast my mind back to the time the invention was made to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.
71. I understand that I am to perform the task referenced in the preceding paragraph without using “hindsight” reasoning. Instead, I was asked to consider the feasibility and combinability of references through the eyes of a person of skill in the art as of November 17, 2005. As I describe below, the individual references contain statements and teachings that motivate those of skill in the art to look to the other references in the combinations I was asked to consider.

72. I understand that relevant considerations for combining references include at least the following:
- (A) Combining prior art elements according to known methods to yield predictable results;
 - (B) Simple substitution of one known element for another to obtain predictable results;
 - (C) Use of known techniques to improve similar devices, methods, or products in the same way;
 - (D) Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
 - (E) “Obvious to try” - choosing from a finite number of identified, predictable solutions with a reasonable expectation of success;
 - (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
 - (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

73. I have kept these considerations in mind when offering the opinions below regarding combinability. As explained below, it is my opinion that those of skill in the art would have combined, with an expectation of success, the combinations set forth below (*i.e.*, *Mehyhay* and *Genatempo*; *Menyhay*, *Genatempo*, and *Raad*; *Menyhay*, *Genatempo*, and *Miyahara*; *Connell*, *Raulerson*, and *Genatempo*; *Connell*, *Raulerson*, *Genatempo*, and *Raad*; and *Connell*, *Raulerson*, *Genatempo* and *Miyahara*). I set forth below how the references and the resulting combinations would appear to a POSA.

***Genatempo* and *Menyhay* through the eyes of a POSA**

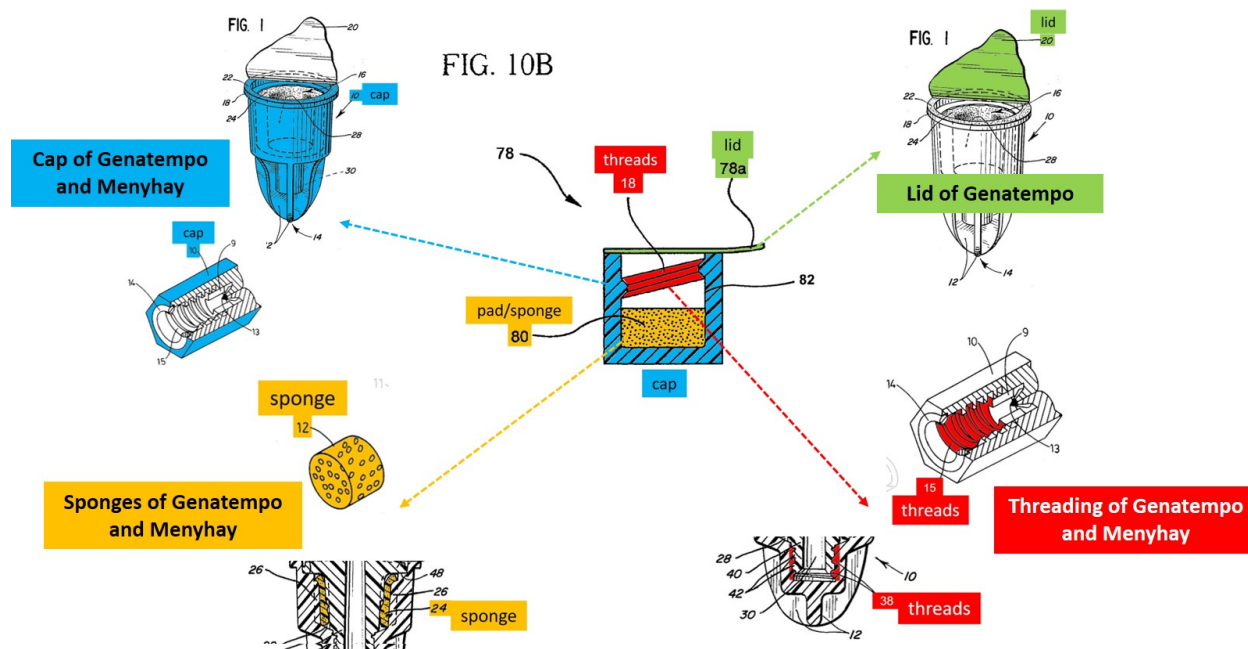
74. I have been asked to consider *Genatempo* and *Menyhay* through the eyes of a POSA. In my opinion, a POSA reading *Genatempo* would have had a basis for modifying the disclosure of *Genatempo* with that of *Menyhay* to arrive at an improved cleaning cap for medical connectors, and would have made those modifications with an expectation of success.
75. *Menyhay* relies upon a frangible capsule within the cap that must be broken during the engagement process with a connector. (Ex. 1007, 6:49-64, Fig. 2, 5). A POSA would understand that *Menyhay's* design ensures that the antiseptic solution contained within the capsule does not evaporate before the solution is needed. However, one drawback of *Menyhay's* approach is the solution does not begin to wet the sponge until after the capsule has been

broken. As a result of this deficiency, the sponge may be partially wet and partially dry when it comes in contact with the connector face; a POSA would understand that this would lead to reduced cleaning power, potentially leading to residual contaminants remaining after cleaning.

76. Conversely, the structure of *Genatempo* provides for a pre-wetted or pre-impregnated sponge, because *Genatempo* includes a peelable lid 20 sealing the antiseptic liquid within cap 10. (Ex. 1006, 2:62-68, Figs. 1 and 3). When combined with *Menyhay's* structure, the lid/pre-impregnated sponge of *Genatempo* ensures that the sponge is fully wetted with the antiseptic solution when the tube connector is threadingly attached to the cap.
77. *Menyhay* does not explicitly disclose disinfecting the threads of *Menyhay's* connector. (Ex. 1007, 6:59-7:3). However, *Menyhay's* design suggests the cleaning of the threading of the connector. In *Menyhay's* design, the cap is screwed into the connector such that the capsule 11 is broken by protrusion 13, releasing solution into the sponge. As the connector continues to be threaded into the cap, the sponge will compress, releasing stored antiseptic liquid that will flow along the channels of the threading thereby cleaning the threading. (Ex. 1007, Fig. 5).
78. *Genatempo* confirms that the cleaning of the threading of the connector is a valuable feature to include in a connector cap. (Ex. 1006, 3:43-45). When

these features are combined to provide full cleaning of the portion of the connector inserted into the cap, the O-ring 14 of *Menyhay* and/or the seal flange 46 of *Genatempo* ensures that the antiseptic solution is retained within the cap during the cleaning process. (Ex. 1006, 3:46-47; Ex. 1007, 6:59-61).

79. The resulting combination suggests to a POSA a cleaner cap/connector system where the connector connects to a patient tube line and includes a septum and external threads to receive a tube connected to an IV, feed tube, or other external component. The threads are also configured to permit threading engagement with the cleaner cap. Within the cleaning cap there would be a sponge that has been pre-impregnated with an antiseptic cleaning solution. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23, Fig. 3). The cap would include threading that would extend inward to engage with threading extending outward from the connector. (Ex. 1007, Figs. 2-3; Ex. 1006, Fig. 3). When the cap is rotated, the threading would cause the advancement of the connector into the cap, leading to the cleaning of the threads and septum at the end of the connector cap. (Ex. 1007, 6:54-7:3, Figs. 2-3). Additionally, the cap would include a peelable lid to ensure that the solution did not prematurely evaporate, spill, or become contaminated prior to use. (Ex. 1006, 2:63-66, Fig. 1).



80. While *Genatempo* and *Menyhay* are silent with regard to the threading length of the disclosed threads, a POSA would understand that this length could be easily modified to a variety of lengths. In particular, because of the seal/o-ring, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal/o-ring of the resulting combination provides this function. A POSA would understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector to a physical stop (e.g., the seal).
81. Each of *Menyhay* and *Genatempo* describe the use of antimicrobial/antibacterial solutions (e.g., antiseptics). (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23). A POSA would understand the disclosure of an antiseptic to suggest antimicrobial solutions as well as antiviral solutions. *Genatempo*

discloses povidone iodine as a free-flowing antiseptic. (Ex. 1007, 1:44-48). *Menyhay* also states that the antiseptic solution “contain[s] povidone iodine and isopropyl alcohol (an antiseptic, bactericidal and virucidal solution).” (Ex. 1007, 6:48-50). A POSA would understand that a variety of other then-known antiseptics could be equally applicable as the povidone iodine of *Menyhay* and *Genatempo*.

82. For example, Exhibits 1015, 1016, and 1017 confirm my opinions that chlorhexidine gluconate and povidone iodine are suitable substitutes that would be readily interchanged in the field of medical device cleaning. For example, Exhibit 1015 relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms. It confirms that one way of cleaning these device surfaces is with “antimicrobial agents or antimicrobial compositions.” (Ex. 1015, 17:47-49). Two of the known solutions for this cleaning include povidone iodine and chlorhexidine, confirming these two as suitable alternatives. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices.
83. Similarly, Exhibit 1016 explains that each of povidone iodine and chlorhexidine are antimicrobial solutions suitable for cleaning the surfaces of indwelling medical devices (e.g., tubes), organic surfaces (e.g., skin), and

other hospital equipment (e.g., hospital pipes, wheelchairs, etc.). (Ex. 1016, Abstract, ¶28, claims 10, 20, 26 and 27).

84. Exhibit 1017 further confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors. (Ex. 1017, 1). Exhibit 1017 further describes work funded by Becton Dickinson UK in this space dating back to 2002. (Ex. 1017, 2). A POSA would have known that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions.
85. These known components of *Genatempo* and *Menyhay* all perform defined tasks in their respective disclosures, and a POSA would understand that the components can be similarly implemented without surprise. Accordingly, I believe that a POSA would have understood the above features of *Genatempo* and *Menyhay* and would have understood that the modifications disclosed above would have been made with an expectation of success.

Menyhay, Genatempo and Raad through the eyes of a POSA

86. I have been asked to consider the technical feasibility and implications of combining, *Menyhay*, *Genatempo* and *Raad*. In my opinion, a person of ordinary skill in the art would have been motivated to combine these references and would have been readily able to combine them with an expectation of success. The basis for the combination of *Menyhay* and *Genatempo* is set forth above.

87. *Raad* confirms that known antiseptic solutions at the time included chlorhexidine and alcohols. (Ex. 1016, ¶28). A POSA would have understood chlorhexidine is the active component of chlorhexidine gluconate (CHG) and is a common way of referring to commercial antiseptic products containing CHG. CHG and alcohol-based antiseptics were well known to a POSA, such that the antiseptic properties were transferable to other uses. (Ex. 1016, ¶28, claims 10, 20). Moreover, *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶28, 78-79, claims 10, 20, 26 and 27).
88. A POSA would have understood that the known antiseptic solutions of *Raad*, which constitutes well-studied ingredients and combinations in the medical field and medical device field, would have been readily used as a known replacement for the povidone iodine explicitly disclosed by *Menyhay* and *Genatempo*.
89. Exhibits 1015 and 1017 confirm my opinions that chlorhexidine gluconate and povidone iodine are suitable substitutes that would be readily interchanged in the field of medical device cleaning. For example, Exhibit 1015 relates to cleaning medical devices that are likely to—or have already—

become contaminated with microorganisms. It confirms that one way of cleaning these device surfaces is with “antimicrobial agents or antimicrobial compositions.” (Ex. 1015, 17:47-49). Two of the known solutions for this cleaning include povidone iodine and chlorhexidine, confirming these two as suitable alternatives. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices.

90. Exhibit 1017 further confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors. (Ex. 1017, 1). Exhibit 1017 further describes work funded by Becton Dickinson UK in this space dating back to 2002. (Ex. 1017, 2). A POSA would have known that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions.
91. The povidone iodine of *Menyhay* and *Genatempo* would be readily replaced with the chlorhexidine of *Raad*, as demonstrated by *Raad*’s interchangeability of these solutions.

Menyhay, Genatempo and Miyahara through the eyes of a POSA

92. I have been asked to consider the technical feasibility and implications of combining, *Menyhay*, *Genatempo* and *Miyahara*. In my opinion, a person of ordinary skill in the art would have been motivated to combine these references and would have been readily able to combine them with an

expectation of success. The basis for the combination of *Menyhay* and *Genatempo* is set forth above.

93. *Miyahara* discloses that a cleaning and protective cap may be securely adhered to a connector with a rotation that is less than one full rotation of the cap, confirming that the threading in the aforementioned combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶¶55-56, Fig. 3).
94. While *Genatempo* and *Menyhay* are silent with regard to the threading length of the disclosed threads, a POSA would understand that this length could be easily modified to a variety of lengths. In particular, because of the seal/o-ring, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal/o-ring of the resulting combination provides this function. A POSA would understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector to a physical stop (e.g., the seal). A reduced number of rotations makes the product easier to use.
95. *Miyahara* does not explicitly disclose that any threading is used, however *Miyahara* does disclose to a POSA that rotational engagement can occur with a rotation less than a full rotation. *Miyahara* depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between

the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56, Fig. 3). *Miyahara* confirms that a rotational distance greater than the inner circumference of the inner cavity is not necessary for advancement or for coupling, and that sufficient cleaning can occur with threading that is shorter (and therefore with less rotational movement) than the internal circumference.

Connell, Raulerson, and Genatempo through the eyes of a POSA

96. I have been asked to consider the technical feasibility and implications of combining, *Connell, Raulerson, and Genatempo*. In my opinion, a person of ordinary skill in the art would have been motivated to combine these references and would have been readily able to combine them with an expectation of success.
97. *Connell* describes a fluid connector cleaning cap that provides a disinfectant to the fluid connector's threads when the two pieces are screwed together. (Ex. 1010, ¶¶101-103). The cap of *Connell* is designed to threadingly mate with the fluid connector. (Ex. 1010, ¶100). The two pieces (cap and connector) are configured to advance towards each other when threaded together. (Ex. 1010, ¶¶77-80). During advancement, prongs of the connector pierce seals that hold an antiseptic solution, releasing the solution such that it is free to flow over the threading and other surfaces of the fluid connector.

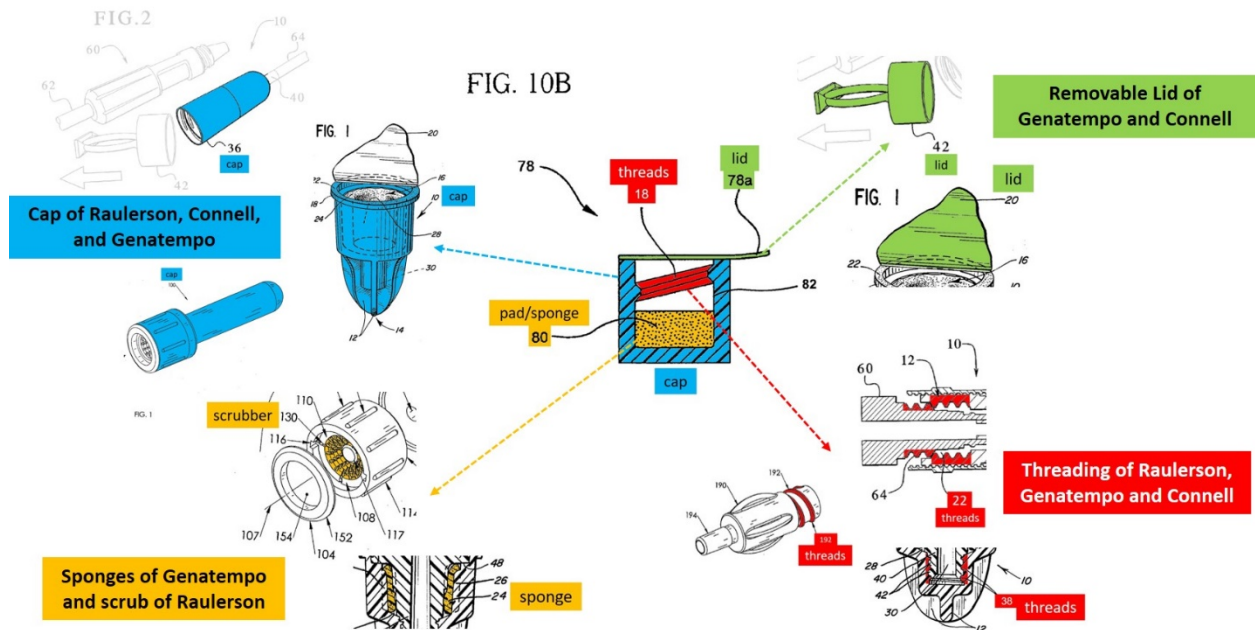
(Ex. 1010, ¶¶15-18, 74, 100-104). However, *Connell*'s cleaning is limited to whatever action is provided by the mere physical contact of the antiseptic solution to the surface. A POSA would understand that in a disposable cleaner, such as that of *Connell*, additional cleaning may be provided by a physical motion such as scrubbing.

98. *Raulerson* discloses this scrubbing action. (Ex. 1011, ¶4). A POSA would understand that *Raulerson*'s design converts rotational energy to cleaning energy, which thereby provides for an antiseptic cleaning of a connector inserted into the cap of *Raulerson*. (Ex. 1011, ¶4). A POSA would further understand that this energy and scrubbing mechanism would lead to a cleaner connector, ensuring that the antiseptic cleaning solution is distributed over all surfaces.
99. *Connell* discloses a small sealed portion with disinfectant (Ex. 1010, ¶100) and *Raulerson* discloses a separate squeezable body for the release of cleaning solution. (Ex. 1011, ¶31). Neither provide for sealed scrubbing element. A POSA would understand that the use of a pre-impregnated absorbent material, such as that of *Genatempo* (Ex. 1006, Abstract), would provide the added benefit of ensuring sufficient wetting of the sponge in advance. In this regard, no dry spots or other deficiencies associated with failure of breaking will occur. *Genatempo* also confirms that additional cleaning due to the migration

of the antiseptic fluid can be achieved. (Ex. 1006, 3:43-45). In this regard, by adopting the pre-impregnated sponge of *Genatempo*, a POSA would understand that additional liquid can be provided that, when the sponge is compressed, is sufficient to release liquid to flow throughout the threading portions of the coupling. Additionally, *Genatempo* describes the use of a removable lid, which a POSA would recognize the necessity of to ensure that the pre-impregnated sponge of *Genatempo* does not dry out or expel its liquid prematurely.

100. In the proposed combination, a connector includes external threads (annotated in red in the figure below) to, *inter alia*, permit threading engagement between an access end of the connector and a disinfectant cap (annotated in blue), and that the cap would include a wetted-sponge (annotated in orange) and a sealable peelable lid (annotated in green). (See *e.g.*, Ex. 1010, ¶¶77-78). The sponge of this combination would be impregnated with an antiseptic cleaning solution. (See *e.g.*, Ex. 1006, 3:22-23, Fig. 3; Ex. 1011, ¶4, Fig. 3). Additionally, in the resulting combination, the cap would include threading to engage with the threading of the connector. (See *e.g.*, Ex. 1010, ¶¶77-78). The threading causes the advancement of the connector into the cap when rotated, and the rotation causes cleaning of the threads and septum at the end of the connector cap through the advancement of the face into the wetted

sponge. (See e.g., Ex. 1010, ¶¶77-78, 80, 101-103, Fig. 5). Additionally, the cap would include a peelable lid to ensure that the solution did not prematurely evaporate or become contaminated prior to use. (See e.g., Ex. 1006, 2:63-66, Fig. 1; Ex. 1010, ¶¶14-15, 68, Fig. 2).



101. While *Connell* and *Genatempo* are silent with regard to the threading length of the disclosed threads, a POSA would understand that this length could be easily modified to a variety of lengths. In particular, because of the seal 46 of *Genatempo*, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal of the resulting combination provides this function. A POSA would understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector to a physical stop (e.g., the seal).

102. *Connell* discloses the use of iodine-containing antimicrobials as a disinfectant. (Ex. 1010, ¶75-76). *Genatempo* describes the use of antimicrobial or antibacterial solutions (e.g., antiseptics). (Ex. 1006, 3:22-23). *Raulerson* discloses antiseptic fluids, for example an isopropyl alcohol, povidone iodine, or hydrogen peroxide, but recognizes any suitable fluid may be used. (Ex. 1011, ¶29). A POSA would understand that a variety of other then-known antiseptics could be equally applicable as the solutions of *Connell*, *Raulerson* and *Genatempo*.
103. For example, Exhibits 1015, 1016, and 1017 confirm my opinions that chlorhexidine gluconate and povidone iodine are suitable substitutes that would be readily interchanged in the field of medical device cleaning. For example, Exhibit 1015 relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms. It confirms that one way of cleaning these device surfaces is with “antimicrobial agents or antimicrobial compositions.” (Ex. 1015, 17:47-49). Two of the known solutions for this cleaning include povidone iodine and chlorhexidine, confirming these two as suitable alternatives. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices.

104. Similarly, Exhibit 1016 explains that each of povidone iodine and chlorhexidine are antimicrobial solutions suitable for cleaning the surfaces of indwelling medical devices (e.g., tubes), organic surfaces (e.g., skin), and other hospital equipment (e.g., hospital pipes, wheelchairs, etc.). (Ex. 1016, Abstract, ¶28, claims 10, 20, 26 and 27). Exhibit 1017 further confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors. (Ex. 1017, 1). Exhibit 1017 further describes work funded by Becton Dickinson UK in this space dating back to 2002. (Ex. 1017, 2). A POSA would have known that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions.
105. These known components of *Connell*, *Raulerson* and *Genatempo* all perform defined tasks in their respective disclosures, and a POSA would understand that the components can be similarly implemented without surprise. Accordingly, I believe that a POSA would have understood the above features of *Connell*, *Raulerson* and *Genatempo* and would have understood that the modifications disclosed above would have been made with an expectation of success.

Connell, Raulerson, Genatempo, and Raad through the eyes of a POSA

106. I have been asked to consider the technical feasibility and implications of combining, *Connell*, *Raulerson*, *Genatempo*, and *Raad*. In my opinion, a

person of ordinary skill in the art would have been motivated to combine these references and would have been readily able to combine them with an expectation of success.

107. *Raad* confirms that known antiseptic solutions at the time included chlorhexidine and alcohols. (Ex. 1016, ¶28). A POSA would have understood chlorhexidine is the active component of chlorhexidine gluconate (CHG) and is a common way of referring to commercial products containing CHG. CHG and alcohol-based antiseptics were well known to a POSA, such that the antiseptic properties were transferable to other uses. (Ex. 1016, ¶28, claims 10, 20). Moreover, *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-28, 78-79, claims 10, 20, 26 and 27).
108. A POSA would have understood that the known antiseptic solutions of *Raad*, which constitutes well-studied ingredients and combinations in the medical field and medical device field, would have been readily used as a known replacement for the povidone iodine explicitly disclosed by *Connell*, *Raulerson*, and *Genatempo*.

109. Exhibits 1015 and 1017 confirm my opinions that chlorhexidine gluconate and povidone iodine are suitable substitutes that would be readily interchanged in the field of medical device cleaning. For example, Exhibit 1015 relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms. It confirms that one way of cleaning these device surfaces is with “antimicrobial agents or antimicrobial compositions.” (Ex. 1015, 17:47-49). Two of the known solutions for this cleaning include povidone iodine and chlorhexidine, confirming these two as suitable alternatives. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices.
110. Exhibit 1017 further confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors. (Ex. 1017, 1). Exhibit 1017 further describes work funded by Becton Dickinson UK in this space dating back to 2002. (Ex. 1017, 2). A POSA would have known that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions.
111. The povidone iodine of *Connell*, *Raulerson*, and *Genatempo* would be readily replaced with the chlorhexidine of *Raad*, as demonstrated by *Raad*’s interchangeability of these solutions.

Connell, Raulerson, Genatempo, and Miyahara through the eyes of a POSA

112. I have been asked to consider the technical feasibility and implications of combining, *Connell, Raulerson, Genatempo, and Miyahara*. In my opinion, a person of ordinary skill in the art would have been motivated to combine these references and would have been readily able to combine them with an expectation of success.
113. *Miyahara* discloses that a cleaning and protective cap may be securely adhered to a connector with a rotation that is less than one full rotation of the cap, confirming that the threading in the aforementioned combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶55-56, Fig. 3).
114. While *Connell, Raulerson, and Genatempo*, are silent with regard to the threading length of the disclosed threads, a POSA would understand that this length could be easily modified to a variety of lengths. In particular, because of the sealing flange of *Genatempo*, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal of the resulting combination provides this function. When these features are combined to provide full cleaning of the portion of the connector inserted into the cap, the seal flange 46 of *Genatempo* ensures that the antiseptic solution is retained within the cap during the cleaning process. (Ex. 1006, 3:46-47). A POSA would understand

that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector to a physical stop (e.g., the seal).

115. *Miyahara* does not explicitly disclose that any threading is used, however *Miyahara* does disclose to a POSA that rotational engagement can occur with a rotation less than a full rotation. *Miyahara* depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶55-56, Fig. 3). *Miyahara* confirms that a rotational distance greater than the inner circumference of the inner cavity is not necessary for advancement or for coupling, and that disinfecting can occur with threading that is shorter (and therefore with less rotational movement) than the internal circumference.

I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like

are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code.

October 11, 2019
Date

Richard Meyst
Richard Meyst