UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C. R. Bard, Inc.,
Petitioner,

v.

Medline Industries, LP,
Patent Owner.

Case IPR2025-00401

U.S. Patent No. 11,661,219

DECLARATION OF KARL R. LEINSING, MSME, PE IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,661,219

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I. INTRODUCTION

1. I have been retained by counsel for Petitioner C.R. Bard, Inc. ("Bard") as a technical expert in connection with the above-captioned *Inter Partes* Review of U.S. Patent No. 11,661,219 ("the '219 patent"), assigned to Medline Industries, LP ("Medline"). I have been asked to provide my opinions and views on the materials I have reviewed in relation to "the '219 patent", and the scientific and technical knowledge regarding the subject matter of the '219 patent before and at the earliest effective U.S. filing date and/or priority date. I understand that Bard is challenging claims 1-7, 9-16 of the '219 patent ("the Challenged Claims"). I submit this expert report to state my opinions regarding the invalidity of the Challenged Claims.

2. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided, particularly in view of any arguments raised by Medline or its experts or additional claim construction orders entered by the Court.

II. PROFESSIONAL BACKGROUND

3. I am President and founder of ATech Designs, Inc., an engineering and design company based in Dover, New Hampshire. I am an engineer with substantial experience in the design and development of a wide variety of medical instruments and devices since 1992 from conception through regulatory approval, manufacturing, and marketing.

4. I hold a Master of Science in Mechanical Engineering from North Carolina A&T State University and a Bachelor of Science Degree in Mechanical Engineering from the University of New Hampshire. I am a licensed professional engineer in New Hampshire (PE License No. 11437).

5. I have designed or developed several medical instruments and devices including IV catheters (U.S. Patent Nos: 7,125,396, 8,029,472 and 8,740,850), a heart band that uses multiple subcutaneous ports attached to tubing (U.S. Patent No: 8,092,363), and devices for delivery and guide catheters (U.S. Patent Nos: 8,951,285 and 8,951,286). All of these designs, including many other medical devices, have packaging of some type. Packaging is a very standard off-the-shelf item in the medical industry. I develop devices from concept to production, so I am involved with market analysis, selection, labeling, testing, and manufacturing of packing used with my devices.

6. I have also done work on urinary catheters, including working on a new product to reduce pain in patients while minimizing risk of infection. As part of my work with ATech Designs, Inc., I consulted with a nurse at Newton-Wellesley Hospital in Massachusetts to design a new kind of urinary catheter based on problems the nurse had identified through her work in the field, particularly patient comfort, CAUTI, selecting the properly sized catheter, and latex allergies. This work was performed in the 2007-2009 timeframe and lasted approximately one year. My

work consisted of analyzing product samples that the nurse would bring me, researching similar products in the market, and researching solutions in analogous devices to find solutions. As part of my research, I studied Bard's intermittent closed-system catheters among other Bard catheter devices. I also studied other Foley and intermittent catheters, many of which came in packages and/or trays.

7. My designs using guide catheters, as mentioned previously, are becoming more and more common as procedures become less invasive and use the femoral artery or veins in the leg to obtain access to remote locations in and around the heart. I have worked on inventions and designs using this approach and these catheters require long lengths and small size devices. The length of these catheters, like standard guide wires, requires the catheter to be coiled in the packaging. My inventions and experience include such guide catheters and use of such associated packaging.

8. I have been named as an inventor on forty-one U.S. patents (others pending). I have received many awards for my designs with one design published on the cover of LIFE Magazine and I was recognized as one of the top 100 medical device professionals in the country by MD&DI Magazine. My curriculum vitae is attached as Exhibit A and includes a list of publications that I have authored in the last 10 years, a list of the patents granted to me, and the cases in which I have testified as an expert at trial, deposition, or report/declaration in the last 5 years.

9. I am being paid at my hourly rate of $500 hour for this matter. I am being paid regardless of the conclusions or opinions I reach. I have no personal or financial stake or interest in the outcome of the present case.

III. BASIS FOR OPINION

10. My opinions and views set forth in this report are based on my education, training, and experience in the relevant field, as well as the materials I reviewed, and the scientific knowledge regarding the same subject matter that existed prior to the earliest effective filing date(s) of the ’219 patent.

11. I have considered information from various sources in forming my opinions. Besides drawing from my experience as a mechanical engineer with experience related to medical devices for the past thirty-two years, I also have reviewed the following documents: (a) the ’219 patent, (b) the prosecution file history of the ’219 patent, (c) parent applications and patents of the ’219 patent cited herein, (d) all prior art references cited herein (including all prior art relied upon in each Ground set forth below), (e) Patent Office proceedings regarding related Medline patents, and (f) the other documents and references as cited herein. I have also reviewed a declaration prepared by Dr. Yun and have spoken with Dr. Yun regarding the subject matter of his declaration. (Ex. 1003.)

IV. PATENT LAW LEGAL STANDARDS

12. I am not an attorney. I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law is as follows.

A. Person Of Ordinary Skill In The Art

13. I understand that U.S. patent law interprets patents and prior art from the point of view of a Person of Ordinary Skill in the Art ("POSA") at the time of the priority date of the Patents-in-Suit. I understand that Medline has asserted that it is entitled to a priority date as of the June 30, 2009 filing of Patent Application No. 12/495,148 in district court proceedings where it has asserted this patent. I note that the '219 patent also cites to the filing of June 3, 2009 as of Provisional Application No. 61/183,269.

14. I further understand that the factors used to determine a person of ordinary skill in the art include: (1) the prior art solutions to the problems presented in the '219 patent; (2) the rapidity with which innovations were being made in the medical device field at the time of the invention; (3) the sophistication of the technology presented in the '219 patent; and (4) the educational level of active workers in the relevant medical device field.

15. Based on my analysis of one or more of these factors and my own personal experience in the medical device field, in my opinion, one of ordinary skill in the art at the time of the invention would be an individual with a bachelor's degree

in mechanical engineering or equivalent technical degree and at least 2 years of experience in the medical device packaging field. One of ordinary skill in the art would not need to be a practitioner, but would have learned about urinary catheterization procedures from those skilled in such procedures (e.g., a nurse or urologist) As of 2009, I met the requirements for one skilled in the art of catheter assembly design and packaging.

16. Based on my educational background and work experience, I am and was familiar with the technology at issue as of at least June 3, 2009, i.e., the earliest possible effective filing date. My educational background and experience also allow me to evaluate what knowledge a POSA, as defined above, would have because I have worked with many people with similar qualifications as well as with medical practitioners having experience and knowledge in the field with such catheter products, e.g., a nurse. My educational background and experience also provide me with insight into the educational level and familiarity of a person working in the field of medical devices and packaging at the time of any of the possible priority dates that are discussed below. I meet the above-mentioned standard for a POSA regardless of the date that is determined as the proper priority date for the asserted inventions.

17. To confirm my understanding as to certain issues relevant to the use of catheter devices and in particular urological catheter device discussed in this report,

I spoke with Dr. Edward Yun, who I understand Bard has retained as an expert witness in this case. I understand Dr. Yun was a practicing urologist before 2009, and specifically during any of the possible priority dates of the patents-in-suit. Although the asserted claims are not limited to Foley catheters (nor urinary catheters) under the Court's construction, the patents relate to method of catheterization procedures that may include urinary catheterizations. Furthermore, much of the prior art discussed in this report is related to packaging for Foley or urinary catheters, and Dr. Yun's knowledge is therefore relevant. I have also reviewed the report of Dr. Yun and have considered his knowledge when forming my opinions.

18. I am familiar with what a POSA would understand from reading the '219 patent or particular cited prior art references. In this report, I am describing what I believe a POSA would have understood as being disclosed or suggested by the document at the time of the '219 patent.

B. Claim Interpretation

19. I understand that when assessing whether a patent claim is invalid, the claims must be properly construed. I understand that several claim terms have been interpreted by the Court and I have used those constructions in my analysis. As to other terms not construed by the Court, I understand and am informed that patent claims should be given their plain and ordinary meaning from the perspective of a person of ordinary skill in the art as of the priority date and must also be read in light

of the specification of the patent and associated prosecution histories. I also understand that the specification is viewed as the best source for understanding a technical claim term.

C. Anticipation/Obviousness

20. I have also been informed and understand that a patent claim is invalid if it is anticipated or rendered obvious by the prior art. I have been informed and understand that a patent claim is anticipated if a single prior art reference discloses each and every element of the claim, arranged as set forth in the claim. I further understand that if a reference fails to expressly disclose one or more elements of the claim, the claim is nevertheless anticipated if the reference inherently discloses the missing elements.

21. I have further been informed and understand that a patent claim is invalid if the differences between the subject matter of the claim and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSA to which the subject matter pertains. I understand that a determination of whether a claimed invention would have been obvious requires taking into consideration certain factors, which include: (a) assessing the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, and (c) the level of ordinary skill in the art.

22. I understand that the claimed subject matter would have been obvious to a POSA if, for example, it results from the combination of known elements according to known methods to yield predictable results, the simple substitution of one known element for another to yield predictable results, use of a known technique to improve similar devices in the same way, or applying a known technique to a known device ready for improvement to yield predictable results. I have also been informed that the analysis of obviousness may include recourse to logic, judgment, and common sense available to a POSA that does not necessarily require explicit disclosure in any reference.

23. I understand that, in determining obviousness, hindsight derived from consideration of the patent should not be used. I further understand that one should consider whether there would have been an apparent reason to combine various element in the fashion claimed by the claimed invention. For example, that can be a teaching, suggestion or motivation to combine. I understand, however, that prior art references need not provide an explicit teaching, suggestion or motivation to combine the elements in the prior art in order for the combination of those elements to be obvious. I understand that the following factors may be considered in evaluating the existence of a reason to combine: (a) the interrelated teachings of multiple references; (b) the effects of demands known to the design community or

present in the marketplace; and (c) the background knowledge possessed by one of ordinary skill in the art.

24. It is my understanding that "prior art" includes patents, pictures, videos, journals, products or devices (also known as "system art"), printed publications in the relevant literature and information that predates the respective priority date(s) of each asserted claim of the Patents-in-Suit.

25. I further understand that secondary considerations, such as praise by others, commercial success, copying, the solution of long-recognized but unsolved needs, and failures of others should be considered in a determination of obviousness, if applicable. I have been informed that secondary considerations of non-obviousness must be balanced against the strength of the case of obviousness and where the inventions represented no more than the predictable use of prior art elements according to their established functions, the secondary considerations are inadequate to establish non-obviousness.

26. I have been informed that the patentee must establish a nexus between the purported evidence of non-obviousness and the merits of the claimed invention. I further understand that where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus.

27. I have been informed that the nexus requirement applies to evidence of commercial success and there must therefore be a nexus between the sales and the merits of the claimed invention. I understand that the patentee must establish that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. I understand that this means that if commercial success is due to an element in the prior art, no nexus exists.

28. I have been informed that just as with the commercial success analysis, a nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis. I understand that not every competing product that arguably falls within the scope of a patent is evidence of copying. I also understand that copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.

29. I have been informed that allegations that a patent solved a long-felt need must be supported by the evidence and that where the differences between the

prior art and the claimed invention are minimal it cannot be said that any long-felt need was unsolved.

30. I have been informed that evidence of industry praise must also have a nexus with the claimed invention and that self-serving statements by the patentee regarding the merits of the claimed invention generally are not given weight.

V. THE ’219 patent

A. Description

31. The ’219 patent was filed on March 28, 2020. It claims priority to a long series of patent applications, the earliest of which are a June 30, 2009 filing of Patent Application No. 12/495,148. The ’219 patent also cites to the filing of June 3, 2009 as of Provisional Application No. 61/183,269. While I have not yet investigated whether each claim is supported by the earlier applications, the prior art I cite in this declaration is from before June 2009.

32. The ’219 patent is directed to “storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices.” (Ex. 1001, 1:43–47.) The specification describes tray 100 shown in Figure 7 (annotated and colorized):

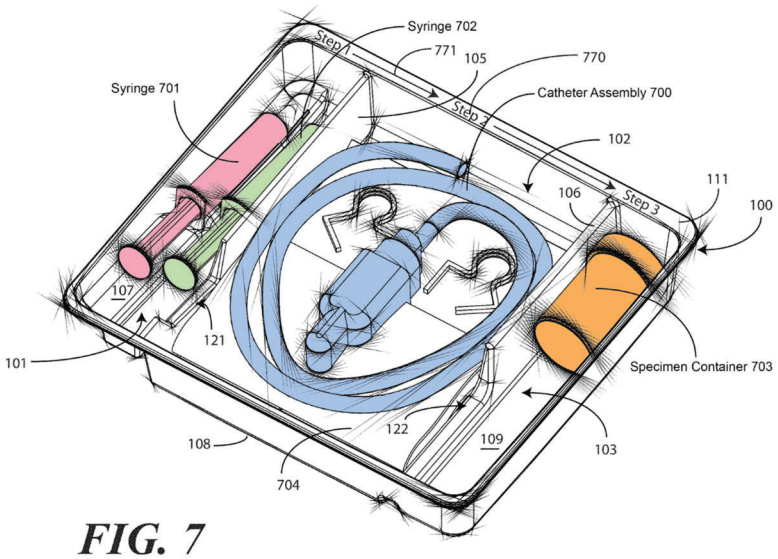


FIG. 7

(*Id*., Fig. 7.)

33. As shown in Figure 7 above, the tray may include equipment such as syringes (provide in a first compartment 101) and a catheter assembly (provided in a second compartment 201).

34. Tray 100 is double-wrapped to ensure that components in the tray remain sterile up to and through their initial use with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. (*Id.* at 11:45–46, 11:51–52, Fig. 10.) In the embodiment of Figure 7, tray 100 includes three compartments (101, 102, 103) adapted to receive various items used in a catheterization procedure. (*Id.* at 5:12–18.) For example, first compartment 101 may accommodate syringes 701, 702 (red, green) containing fluids such as sterile water or lubricants. (*Id.* at 4:18–21, 9:24–26.) Second compartment 102 may accommodate a medical device, such as catheter assembly 700 (blue) and towel 704. (*Id.* at 9:26–28.) The third compartment may

103 accommodate other equipment such as a specimen container 703 (orange) for capturing samples taken from the patient via catheter 700. (*Id.* at 4:22–23, 5:64–65.) Additional objects can be included with the tray, including swab sticks, a securement device, printed instructions, and so forth. (*Id.* at 5:46–51.)

B. The Challenged Claims

35. The challenged claims are claims 1-7 and 9-16. Among the Challenged Claims, only claims 1 and 13 are independent. For ease of reference, Petitioner has labeled the limitations of claims 1 and 13 as follows:

Claim 1	
1.p	A medical procedure kit, comprising:
1.a	a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber;
1.b	a container of lubricating jelly disposed within the single layer tray; and
1.c	a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit;
1.d	wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly;
1.e	the container of lubricating jelly comprising a syringe containing the lubricating jelly; and
1.f	the syringe situated within the lubricating jelly application chamber.

Claim 13	
13.p	A medical procedure kit, comprising:
13.a	a first syringe and a second syringe;
13.b	a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter;
13.c	a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly,
13.d	the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber;
13.e	and an outer packaging disposed about the single layer tray; wherein:
13.f	one of the first syringe or the second syringe contains lubricating jelly;
13.g	another of the first syringe or the second syringe contains water;
13.h	the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure; and
13.i	the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe.

VI. INTER PARTES REVIEW OF RELATED MEDLINE PATENTS

A. 2015 IPRs

36. I understand that Bard filed inter partes review ("IPR") petitions related to three Medline patents that are related to the '219 patent: U.S. Patent Nos. 8,448,786 ("'786 patent"), 8,678,190 ("'190 patent"), and 8,631,935 ("'935 patent"). Specifically, I understand that the '219 patent claims priority to the applications that

led to the ’190 and ’935 patents, and that the ’786 patent also claims priority to these same applications. I understand that the Board instituted IPR of certain claims of the ’190 and ’935 patent, but not the ’786 patent.

37. With respect to the ’786 patent, I understand that the Board concluded that the cited prior art did not disclose the method step of “unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly.” (IPR2015-00509, Paper 11 at 9-12 (emphasis added).) I note that there is no similar limitation in the challenged claims of the ’219 patent.

38. With respect to the ’190 patent, I understand the Board instituted review of claims 1-7, 9, and 11-13, but not of claims 10 and 14-18. The Board denied institution of those claims because the cited prior art did not teach “an opening in a first barrier separating the first compartment from the second compartment.” (IPR2015-00514, Paper 10 at 17-21.) I note that none of challenged claims recite an opening in a barrier. Specifically, I understand that IPR was instituted based on a combination including Serany, which is also utilized in every ground in this request. I understand that Medline cancelled the instituted claims via a request for adverse judgment in response to the institution of IPR. (IPR2015-00514, Papers 14-15.)

39. With respect to the ’935 patent, the Board instituted review as to claim 21 based on a combination including Rauschenberger. For the rest of the claims, the Board was not persuaded “why one of ordinary skill would have moved the syringe

(that replaces the lubricant packet of Rauschenberger) from the main compartment of tray 10 of Rauschenberger to channel 21, in which the catheter is disposed." (Ex. 1022 (IPR2015-00513, Paper 9) at 27.) I understand that Medline cancelled claim 21 via a request for adverse judgment in response to the institution of IPR. (IPR2015-00514, Papers 9, 11.)

B. 2019 IPRs

40. I understand that Bard filed IPR petitions against four more related Medline patents in five proceedings and that IPR was instituted as to each patent: U.S. Patent Nos. 9,745,088 ("'088 patent"), 9,795,761 ("'761 patent"), 9,808,596 ("'596 patent"), and 9,808,400 ("'400 patent"). Specifically, I understand that the '219 patent claims priority to the same applications that led to the '088, '761, '597, and '400 patents.

41. With respect to the '400 patent, on June 3, 2020, the Patent Trial and Appeal Board found all challenged claims unpatentable as obvious based on Solazzo in view of Serany and U.S. Patent No. 3,965,900 to Boedecker. (IPR2019-00208, Paper 57 (Ex. 1023) at 35.) For example, the PTAB concluded that Serany disclosed the claimed "catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptable" as well as the claimed arrangement of these components. (Ex. 1023 at 6, 15.) And the Board also concluded that it would have been obvious to substitute Serany's closed-system Foley catheter for Solazzo's

catheter because it "would render Solazzo's kit more versatile." (*Id.* at 21.) Additionally, the Board found that an "ordinarily skilled artisan would have considered it to be obvious to place the lubricant in a syringe as a known substitute used for a known purpose." (*Id*. at 17.)

42. I note that the Board extensively discussed Bard and Medline's arguments regarding whether it would have been obvious to include a closed-system Foley catheter in the tray of Solazzo and the reasons to do so, and the Board ultimately agreed with Bard and rejected Medline's counter-arguments:

> First, Patent Owner argues that "fundamental differences" between Solazzo and Serany would counsel against modifying Solazzo to hold Serany's fluid receptacle for its Foley catheter. PO Resp. 24–27. Patent Owner argues that because Solazzo's Foley catheter 120 is an "open design," which is not connected to a fluid receptacle, an ordinarily skilled artisan would not alter Solazzo's catheter into a closed system catheter. Id. at 24–25 (citing Ex. 2041 ¶¶ 164, 166–173). The testimony from Ms. Chiappetta, upon which Patent Owner rests, points out that open and closed catheter systems have different uses and that commercial open systems may not have space to accommodate a catheter bag. Ex. 2041 ¶¶ 166–173.
>
> Petitioner argues that an ordinarily skilled artisan would have found it obvious to substitute a closed-catheter as described by Serany for Solazzo's open-catheter 120 and place it in Solazzo's recessed area 3. Id. at 43–45. Petitioner contends that an ordinarily skilled artisan would have been motivated to do so because modifying Solazzo to incorporate a "ready for use" closed-catheter system would simplify Solazzo's catheterization procedure and reduce the risk of infection for patients. Id. (citing Ex. 1002 ¶¶ 171–173, 390; Ex. 1003 ¶ 35; Ex. 1004, 239 ¶ 29;

Ex. 1006, 1:20–23, 3:26; Ex. 1010, 51, 52). Petitioner also contends that including a closed-catheter assembly in Solazzo's kit would render Solazzo's kit more versatile because the modified kit could be used for both permanent catheterization and irrigation procedures. Id. at 45 (citing Ex. 1002 ¶ 174; Ex. 1003 ¶¶ 41, 42).

Ms. Chiappetta admits that closed catheter systems are "always better" for reducing the incidence of catheter acquired urinary tract infection ("CAUTI"). Ex. 1073, 81:23–82:9. Accordingly, her testimony supports Petitioner's position that modifying Solazzo's Foley catheter from an open to a closed system (i.e., with the bag described by Serany) would have been desirable to skilled artisans. Therefore, Petitioner persuades us that an ordinarily skilled artisan would have been motivated and have considered it obvious to incorporate the closed catheter concept from Serany into Solazzo's kit.

Second, Patent Owner argues that it would not have been obvious to modify Solazzo's Foley catheter to a closed system because doing so would render Solazzo "inoperable for its intended purpose." PO Resp. 27–34. More specifically, Patent Owner contends that including a bag in Solazzo's kit would require enlarging Solazzo's tray to such an extent that it could no longer be used between a patient's legs, the allegedly fundamental purpose of Solazzo's design. Id. at 28 (citing Ex. 2040 ¶¶ 97–103; Ex. 2041 ¶ 166; Ex. 1005, 1:7–13, 3:9–11, 3:66–4:3).

Petitioner persuasively establishes that the expert testimony relied upon by Patent Owner is inconsistent with testimony elicited on cross examination. Reply 5–7. For example, Dr. Singh testified that Solazzo's tray would accommodate evacuation tubing, which would be three to five feet long. Ex. 1074, 185:17–189:19. Mr. Plishka and Dr. Yun both testified that Solazzo being able to accommodate such a length of tubing would necessarily mean that Solazzo could also accommodate a closed catheter assembly, which would include tubing of three to

> four feet. Ex. 1070 ¶ 8; Ex. 1071 ¶ 35. Ms. Chiappetta testified that a tapered, open system tray, such as Solazzo's tray, could also accommodate a closed-system Foley catheter. See Ex.1073, 162:1–165:5 (contradicting her declaration testimony that a closed Foley catheter does not fit in tapered tray for use between a patient's legs made by Bard).
>
> Even if we were to conclude that a primary purpose of Solazzo's tray were to fit between a patient's legs, Petitioner has shown that placing a closed Foley catheter in such a tray would not have frustrated that purpose. Accordingly, Petitioner persuades us that an ordinarily skilled artisan would have considered it obvious to modify Solazzo's tray to include a drainage bag connected to its Foley catheter (i.e., a closed system).

(Ex. 1023 at 20-22.)

43. Additionally, the Board considered Medline's secondary considerations evidence but concluded that "Patent Owner has not established either a presumed nexus or nexus in fact between the claimed subject matter and the objective evidence of non-obviousness." (*Id*. at 26.) For example, the Board noted that Medline's secondary considerations evidence was directed to a "single level tray" claim element, but that "single layer trays in catheterization kits were well known in the prior art." (*Id.* at 24-25.) The Board also rejected Medline's arguments that commercial embodiments of the claimed inventions had reduced catheter associated urinary tract infections, because "Petitioner persuasively demonstrates that CAUTI rates declined steadily before single level trays gained market share and thus decreased for reasons unrelated to the claimed tray." (*Id.* at 25-26.) The Board

found Medline's data to be "cherry-picked" and its expert testimony to be "discredit[ed]" because it ignored "a change in the definition of CAUTI." (*Id.*)

44. I understand that the Board initially determined that none of the challenged claims of the '088, '596, and '761 patents were unpatentable as obvious based upon the instituted grounds. However, I understand that the Federal Circuit reversed with respect to the Board's Decisions as to the '088 and '596 patents and remanded the decisions back to the Board for further consideration. For example, I understand that the Federal Circuit found that it would have been obvious to place two syringes within the first compartment of Solazzo and would have been obvious to arrange those syringes at different heights in accordance with their order of use. *C. R. Bard, Inc. v. Medline Indus. Inc.*, 2021 WL 3574043, at *7-9 (Fed. Cir. Aug. 13, 2021).

45. I understand that the Federal Circuit did not reverse the Board's conclusion that Solazzo fails to disclose that its first compartment is a lubricating jelly application compartment. The Board had found that Solazzo "expressly" designates different compartments (31 and 33) as "lubricating wells" to facilitate lubrication of the catheter, and thus the use of "deep compartment 27 … to apply lubricant is incongruous with Solazzo's express teaching to use wells 31, 33 to lubricate the tip of the catheter." (Ex. 1016 at 21-22 (citing Solazzo at 4:21-25).) I

note that I do not rely on the Solazzo grounds as meeting any claim that requires lubricating the catheter in the same compartment that stores the syringes.

46. On remand, I understand that the Board invalidated all remaining claims with the exception of those claims requiring lubricating the catheter in the same compartment that stored the syringe. Specifically, on remand from the Federal Circuit, on September 30, 2022, the Board found claims 1, 2, 6, 8-10, 16, 25-27, 29-37, 39-58, 60-74, 76-90, and 92 of the '088 patent unpatentable as obvious in view of Solazzo, Serany, and Disston as well as claims 7-8 and 11-13 of the '596 patent. (IPR2019-00035, Paper 100; IPR2019-00036; IPR2019-00223, Paper 87.) Public versions of those decisions issued on November 23, 2022. (Exs. 1014-16.) The obviousness combinations also relied on Franks-Farah (teaching printed instructions) for certain claims. (Ex. 1015 at 57-58.) Only claims 7, 17-19, 28, and 38 were not found unpatentable as each of these claims required a lubricating jelly application chamber in the first compartment, which the Board found was not disclosed by compartment 27 of Solazzo. (Ex. 14 at 29-32.) Yet, the Board found unpatentable as obvious claims that required "the single layer tray comprising a lubricating jelly application compartment" because these claims were met by "Solazzo's lubricating wells 31, 33." (Ex. 36 at 24.)

47. Additionally, I understand the PTAB again reviewed Medline's evidence for each of the secondary considerations factors and found it lacking. The

Board again noted the single layer tray feature as well as arranging syringes in their order of use was in the prior art. (Ex. 1014 at 54-76; Ex. 1015 at 40-57.) With respect to long-felt need, the PTAB found that Medline could not show that the claimed invention contributed to a reduction in CAUTI: "Petitioner persuasively demonstrates that CAUTI rates declined steadily before single level trays gained market share and thus decreased for reasons unrelated to the claimed tray." (Ex. 1014 at 63-65 (also describing Medline's internal CAUTI data as "cherry-picked."). The Board also found that the copying factor did not weigh strongly in favor of non-obviousness. The Board recognized there were some commonalities between the trays (i.e., both single layer), but noted that the layout of the SureStep tray was more similar to the Rauschenberger patent from the 1970s than the ERASE CAUTI tray. (Ex. 1014 at 65-69.)

48. As for failure of others, the PTAB concluded that Bard relying on a design contest in coming up with the Accused SureStep tray was not indicative of any failure on the part of Bard. (Ex. 1014 at 69-70.) Finally, the Board found that other factors, including brand loyalty, GPOs, price, and quality (and not Medline's claimed inventions) drove the commercial success of the Accused SureStep trays and Medline's own Foley catheter tray products. (*Id.* at 70-76.)

49. With respect to the '596 patent, on November 23, 2022, the Board found on remand that claims 7 and 11-13 were unpatentable as obvious based on

Solazzo in view of Serany. (Ex. 1016 at 40.) Claim 8 was found unpatentable based on Solazzo in view of Serany and U.S. Patent No. 3,965,900 to Boedecker. (*Id.*) The Board considered Medline's secondary considerations evidence for a second time, but concluded that "Patent Owner's objective evidence of nonobviousness does not weight significantly against a conclusion of obviousness for any claim at issue on remand." (Ex. 1016 at 20-39.)

VII. PROSECUTION HISTORY

50. The '219 patent was filed on March 28, 2020 with independent claims 1, 13, and 18 each directed to a medical procedure kit comprising a single layer tray. (Ex. 1004 at 50-52.) On April 8 2020 and June 3, 2020, the Board issued in its initial Final Written Decisions ("initial FWDs") with respect to the related '088 and '596 patents—finding initially that a combination of Solazzo and Serany did not disclose or render obvious any of the challenged claims, such as a requirement of two syringes disposed within a first compartment. (IPR2019-00035, Paper 73 at 26; IPR2019-00036, Paper 73 at 16; IPR2019-00109, Paper 69 at 29; IPR2019-00223, Paper 58 at 17.)

51. On June 22, 2021, Medline made a preliminary amendment to the claims that added elements to certain claims that the Board had initially found missing from Solazzo and Serany such as "a first compartment for receiving the first

and the second syringe and a second compartment for receiving at least a portion of the medical assembly." (Ex. 1004 at 221-26.)

52. On July 14, 2020, Medline submitted an IDS that included the Board's "Initial FWDs in the Prior IPRs. (Ex. 1004 at 209-10.)

53. On September 13, 2022, the Patent Examiner issued an office action, rejecting nearly all pending claims under nonstatutory double patenting in view of the '088 and '596 patents. (Ex. 1004 at 214-35.) The Office Action did not discuss Solazzo, Serany, Rauschenberger, or Numata. (*Id.*)

54. On September 30, 2022, the Board issued Remand Decisions in IPR2019-00035 (Ex. 1014) and IPR2019-00036 (Ex. 1015), and IPR2019-00223 (Ex. 1016). In the Remand Decisions, the Board found nearly all of the remaining challenged claims to be unpatentable as obvious over a combination of Solazzo and Serany. (Exs. 1014-16.)

55. On October, 20, 2022, February 13, 2023, and April 6, 2023, Medline filed IDSs. (Ex. 1004 at 475-78, 672-75, 760-61.) But none of the IDS included the Remand Decisions, which were not submitted during the prosecution of the '219 patent. (Ex. 1004 at 475-78, 672-75, 760-61.)

56. Medline filed a terminal disclaimer on February 13, 2023 to overcome the rejections. (Ex. 1004 at 585-86.)

57. On February 24, 2023, a Notice of Allowance issued that discussed Solazzo and Serany. However, the Examiner did not have the benefit of the 2022 IPR Final Written Decisions on Remand (Ex. 1014-1016) when he issued his Notice of Allowance. (Ex. 1004 at 686-91.) The Notice of Allowance states that "Solazzo, the closest art of record, lacks a syringe containing lubricating jelly wherein the syringe is situated within the lubricating jelly application chamber." (Ex. 1004 at 689.) But independent claim 13 includes no such requirement so the Examiner likely rejected Solazzo based on other reasons (such as the reasons provided in the Initial FWDs) that were then reversed on remand by the Board.

58. The Examiner also did not discuss Rauschenberger in the Notice of Allowance (or anywhere else in the prosecution history of the '219 patent). (Ex. 1004 at 686-91.) The Examiner also did not discuss Numata in the Notice of Allowance, which I understand was not submitted during the prosecution of the '219 patent. (*Id.*)

59. Following the Notice of Allowance, Medline made minor amendments to the claims. (Ex. 1004 at 734-40.) The Examiner thus issued a second Notice of Allowance on April 14, 2023. (Ex. 1004 at 764-73.) The Examiner distinguished Solazzo for the same reasons as in the February 2023 Notice of Allowance, which failed to account for claim 13. (Ex. 1004 at 770.) The Notice of Allowance does not discuss Rauschenberger or Numata. (Ex. 1004 at 764-73.)

VIII. CLAIM CONSTRUCTION

60. For each of the claim terms in the ’219 patent, I have applied the plain and ordinary meaning of the remainder of those terms.

IX. PRIOR ART

61. The Foley catheter was originally designed by Dr. Frederic Foley in collaboration with Charles Russel Bard. This design was adopted by C. R. Bard, who manufactured the first prototypes. Bard placed the Foley catheter device on the market in 1933. (See Foley F.E.B., “A hemostatic bag catheter: one piece latex rubber structure for control of bleeding and constant drainage following prostatic resection.” Journal of Urology, 38:137–139 (1937).)

62. At the time of the alleged invention in 2009, methods of using a catheter package assembly, including catheter package assemblies containing urinary and Foley catheters, were well-known and well-developed. Indeed, as noted below, Bard itself has patents from the 1960s on all-in-one Foley catheter kits. I understand from my own medical device experience and from Dr. Yun that Foley catheters must be maintained in a sterile condition because they are inserted into a patient’s body. (Ex. 1003 ¶¶ 27-31.) Consequently, Foley catheter trays were often wrapped in a CSR wrap, enclosed in an outer packaging (typically a plastic bag that is thermally sealed), and run through a sterilization process. Indeed, as disclosed by Serany, this method of packaging was known by the 1960s. (Ex. 1009 at 1:8-30; 1:59-2:20.)

63. Medical device trays are packaged to allow trays to be shipped while holding the components inside the tray and may also hold the components within specific compartments of the tray. Bags, wraps, sealable lids, sleeves, and other forms of outer packaging were all common features of medical device trays decades before the earliest priority date of the claimed inventions. Often when components inside the tray must remain sterile prior to the packaging being opened, a sterile wrap encloses the tray to hold the components in place and help maintain the sterility of components within the tray in combination with a sealed bag around the wrap. This wrap can be called a Central Sterile Reprocessing wrap or "CSR wrap."

A. U.S. Patent No. 7,278,987 to Solazzo ("Solazzo")

64. I understand that U.S. Patent No. 7,278,987 was issued to Anthony Solazzo. As indicated on the face of the patent, it issued on October 9, 2007. (Ex. 1005.)

65. I understand that, because Solazzo issued on October 9, 2007, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

66. Solazzo discloses a single layer Foley catheterization/irrigation tray with compartments 3 and 17 as shown in annotated Figures 1 and 8 below:

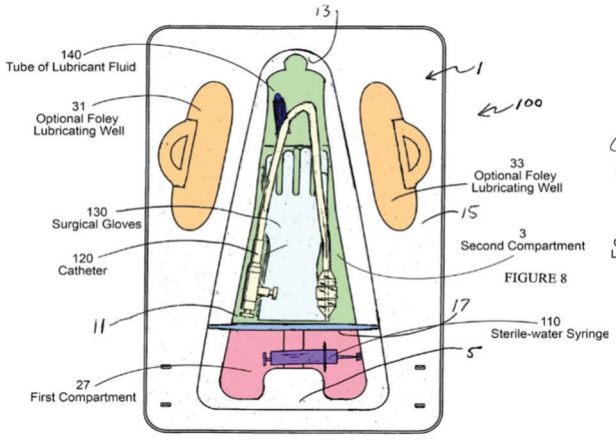


FIGURE 8

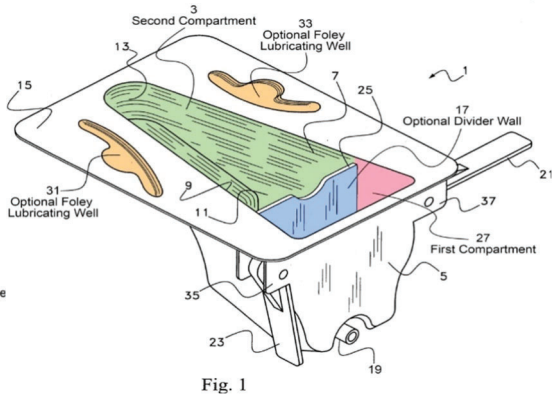


Fig. 1

(Ex. 1005 at Figures 1 and 8.)

67. As shown in the Figures above, the tray of Solazzo has multiple compartments, including compartment 3 ("recessed area 3"), compartment 27, and lubrication wells 31, 33. (Ex. 1005, 4:15-25; Fig.1.) Figure 8 depicts an inflation syringe in compartment 27 (a first compartment) and the Foley catheter and lubricant in compartment 3 (a second compartment). (*Id.*) Solazzo also discloses an "irrigation syringes," but does not expressly state where the irrigation syringe is stored. Solazzo further discloses additional equipment that is used in a urinary catheterization procedure that is provided in the tray including gloves, evacuating tubing, and antiseptic solutions. (Ex. 1005, 3:14-24, 4:1-8; Fig. 8.)

68. Solazzo's tray has a terraced bottom 11 having low area 11A and shallow area 11B as shown in annotated Figure 2 below. (Ex. 1005, 3:61-66; Fig. 5.)

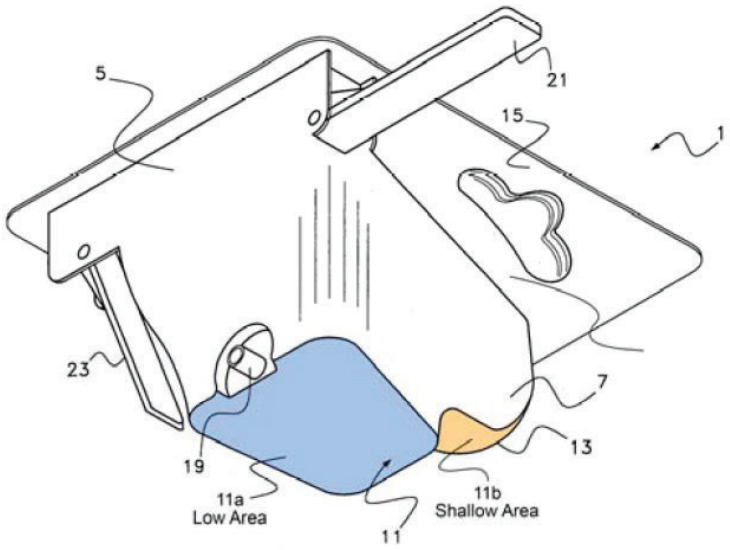


Fig. 2

(Ex. 1005, 3:61-66; Fig. 5.)

69. Accordingly, as configured in Figure 8, the lubricant may be stored in a higher portion of the tray (shallow area 11b) and the water syringe in a lower portion of the tray (low area 11a). The tray of Solazzo can fit between the legs of "[a] patient requiring a urological procedure." (Ex. 1005, 1:8-12, 3:66-4:10, 4:26, 4:32-33; Fig.1.) Solazzo also describes the basic steps of a Foley catheterization procedures: it notes that a surgeon proceeds to "evacuate the bladder of its contents, urine and/or clots" using kit 100 by wearing the gloves, lubricating and inserting the catheter, and inflating the Foley catheter balloon. (Ex. 1005, 4:32-33, 46-48.)

B. Japanese Patent Application Publication No. 2006-131284 to Numata ("Numata")

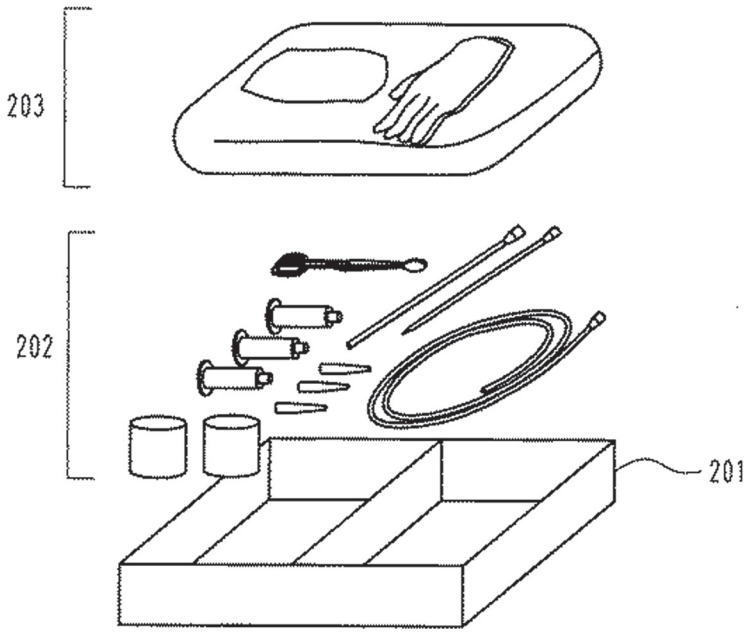
70. I understand that Japanese Patent Application Publication No. 2006-131284 to Shigeki Numata ("Numata") was published on May 25, 2006. (Ex. 1006.) In this declaration, I rely on a certified translation of Numata. (Ex. 1007.)

71. I understand that because Numata was published on May 25, 2006, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b). This patent application was also not a listed cited reference during the prosecution of the '219 patent.

72. Numata discloses a catheter kit with the equipment, including a catheter and multiple syringes, stored in a multi-compartmented single layer tray. (Ex. 1007 at Abstract; Figure 4.) Specifically, Numata is directed to a package body for storing medical instruments, such as catheters, that allows the removal of such instruments from the package while maintaining an aseptic state. (Ex. 1007 at Abstract; ¶¶ 0019, 31.) "[T]he instruments to be used for a catheter procedure are packaged together in **a single tray**" in order "to reduce the effort of purchasing and arrangement and prevent usage errors and preparation errors." (Ex. 1007 ¶¶ 0005 (emphasis added).) Numata therefore teaches the storage of medical equipment such as a catheter and syringes in a single tray to help prevent errors and maintain aseptic technique.

73. Figure 4 below shows the single layer tray of Numata with multiple compartments for storing the equipment within:

(FIG. 4)



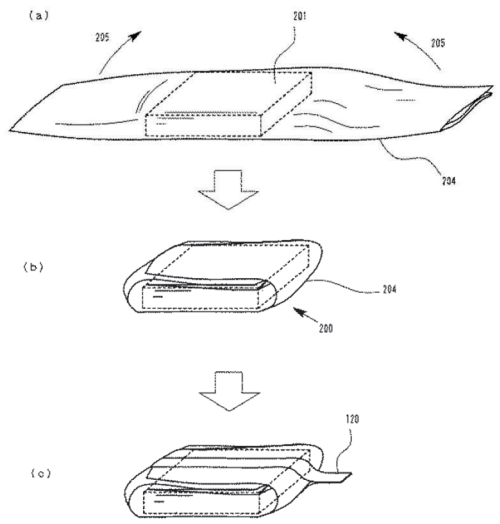
(Ex. 1007 at Fig. 4.)

74. Specifically, "tray 201" stores "medical instruments 202 such as catheters, syringes, injection needles, forceps and degreasing cotton." (Ex. 1007 ¶¶ 0031.) There are additional items 203 (placed above the medical instruments 202) that include items such as "gloves," "a drape," etc. (Ex. 1007 ¶¶ 0031.)

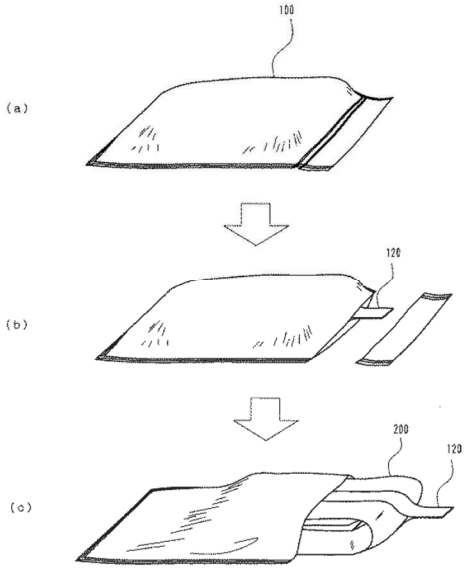
75. As with many of the prior art references discussed in my declaration, Numata utilizes the well-known solution of wrapping the tray in a wrap and then sealing the tray in a bag to keep the contents within sterile. Specifically, Numata's

tray is wrapped in a cover cloth 204 and sealed inside a "packaging bag 100" as shown in Figures 5 and 7 below:

(FIG. 5)



(FIG. 7)



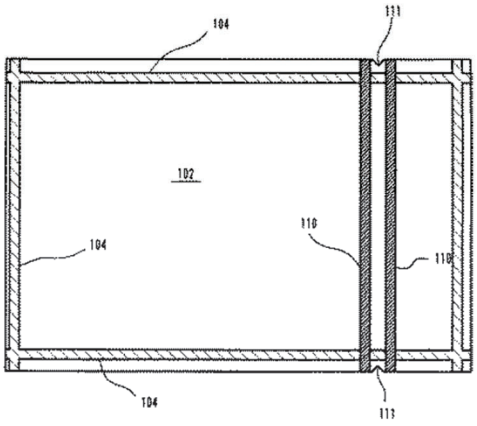
(Ex. 1007 at Abstract; Figures 5, 7; ¶ 0006-0010; 0019-02; 0031-32)

76. The packaging invention of Numata can be employed to store various types of medical equipment, and therefore is broadly directed to a "package body for storing medical instruments" for procedures "employing disposable medical instruments such as catheters." (Ex. 1007 ¶0001.) The exemplary embodiment of Numata is a kit that stores "medical instruments used for surgery, such as catheters for introduction into blood vessels and their accessories." (Ex. 1007 ¶ 0037.) "However, the invention is also applicable to any other medical products . . . which are sold sealed within packaging material in a sterilized state." (Ex. 1007 ¶ 0037.)

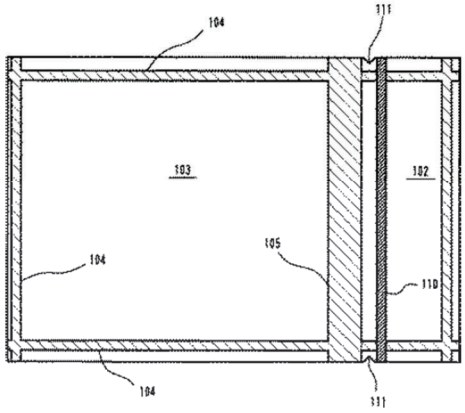
77. Numata's packaging solution allows for the removal of sterile medical instruments from inside a packaging bag "without directly touching the instruments with one's hands." (Ex. 1007 ¶ 0004.) Numata describes a problem that it seeks to solve as follows, noting that "physicians who have undergone thorough disinfection for direct contact with a patient … are not allowed to touch the outside of the packaging" because it "may be microbially contaminated." (Ex. 1007 ¶ 0004.) Because of the potential for contamination from the outside of the packaging, the removal of sterile instruments from a medical kit was traditionally performed instead by persons who have not undergone a "thorough disinfection." (Ex. 1007 ¶ 0004.) However, as persons who have not undergone a "thorough disinfection" cannot directly touch the sterile instruments, it was necessary to remove them from the package "using tools such as forceps," which is cumbersome. (Ex. 1007 ¶ 0004.)

78. To solve the problem identified above, Numata's kit allows for the removal of the medical instruments from the packaging bag without touching them. (Ex. 10047 ¶0009.) As shown in Figures 1 and 3 below, Numata discloses a packaging bag with a notch 111 and a tape [110] forming a cut line along the notch." (Ex. 1007 ¶ 0020.)

(FIG. 1)

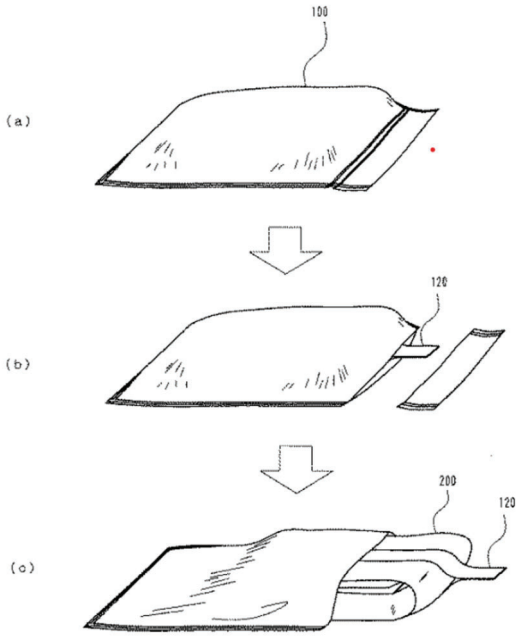


(FIG. 3)



By "cutting off the end of the medical product storage pack 100 from the notch 111," "the end of band 120" is exposed as shown in Figure 7(b).

(FIG. 7)



(Ex. 1007 ¶ 0036; Fig. 7.) The medical product 200 can then be removed from the packaging bag by "pulling the band 120." (Ex. 1007 ¶ 0036.) With this operation,

medical product 200 can be removed without the need to "directly touch[] the medical product 200 with one's hands." (Ex. 1007 ¶ 0036.)

C. U.S. Patent No. 3,329,261 to Serany ("Serany")

79. I understand that U.S. Patent No. 3,329,261 was issued to Frank J. Serany. As indicated on the face of the patent, it issued on July 4, 1967. (Ex. 1009.)

80. I understand that because Serany issued on July 4, 1967, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b). Serany is assigned to C. R. Bard, Inc.

81. Serany discloses an all-in-one Foley catheter kit with common equipment used to perform a Foley catheterization. (Ex. 1009 at Fig. 6.) Specifically, the catheterization package of Serany includes a top tray and a bottom tray, as shown in Figure 6 (annotated with color and description):

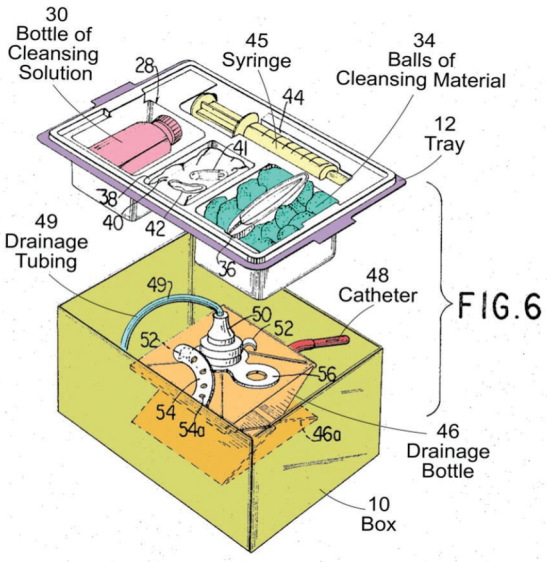


FIG.6

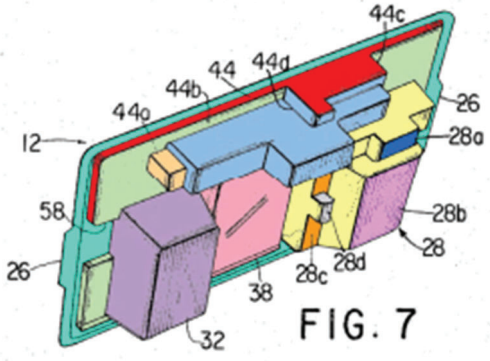


FIG. 7

(Ex. 1009 at Figs. 6-7.)

82. Within the kit of Serany is a Foley catheter 48 that is pre-connected to a drainage bottle 46 via drainage tubing 48 (also known as a closed-system catheter) (Ex. 1009 at 3:23-26, Fig. 6.) As shown in Figure 6 above, "[t]he catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex. 1009 at 3:32- 34.) The top tray (12) of Serany has multiple compartments to "suitably accommodate components for catheterization." (Ex. 1009 at 2:39-40.) As shown in Figure 7 of Serany above (annotated with color and description), the compartments are contoured to fit the components stored in the tray.

83. Serany discloses a tray enclosed in a wrap 14 and provided in an outer packaging 16. (Ex. 1009 at 1:60-66, Figs. 1-3.)

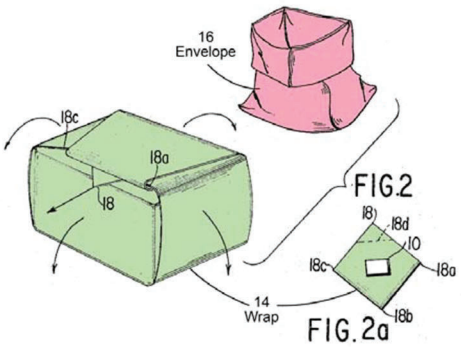


FIG.2

FIG.2a

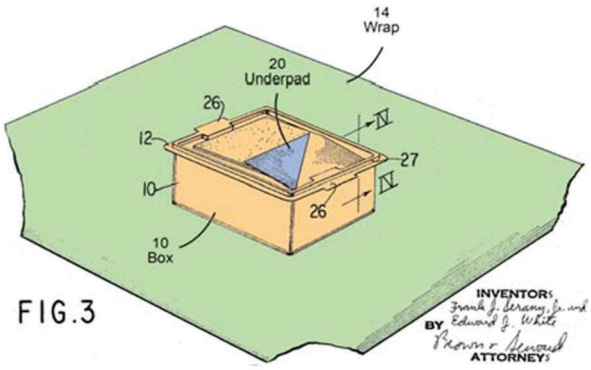


FIG.3

84. The wrap 14 when unfolded "around the box … serves as a sterile field and work area for the remaining operations to be described." (Ex. 1009 at 2:1-20.) The bag (envelope 16) helps maintain the sterility of the components within the kit:

> Referring to the drawings, a box 10 having an open top with a tray 12 mounted thereon is enclosed within a wrap 14, the entire assembly being encased within an envelope 16. The envelope 16 seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope.

(Ex. 1009 at 1:59-66.)

85. Serany includes an inflation syringe 45 for inflating the retention balloon of the Foley catheter and lubricating jelly 40 for lubricating the Foley catheter, and states that "[e]verything is available in the proper order of use" and that the "sterile components" of the kit are "packaged in their order of use." (Ex. 1009 at 1:23-30, 3:1-7, Fig. 6.) Serany further states that the kit "provides the convenience of having all the components arranged in a logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:31-35.) Serany's package also includes a waterproof underpad 20, gloves 22, fenestrated drape 24, cleansing solution bottle 30, rayon balls 34, forceps 36, lubricating jelly pouch 40, safety pin 41 and rubber band 42. (Ex. 1009 at 2:21-3:32, Fig. 6.)

D. U.S. Patent No. 3,166,189 to Disston ("Disston")

86. I understand that U.S. Patent No. 3,166,189 was issued to Hamilton S. Disston. As indicated on the face of the patent, it issued on January 19, 1965. (Ex. 1008.)

87. I understand that, because Disston issued on January 19, 1965, more than one year prior to the earliest alleged priority date of the '219 patent (June 3,

2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b). Disston is assigned to C. R. Bard, Inc.

88. Disston which discloses an all-in-one Foley catheter tray provided in a single tray, was filed on filed on March 26, 1963. Disston "provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled." (Ex. 1008, 1:59-67, 2:60-63, Figs. 2-3.) Disston discloses a sealed sterile catheterization package with the equipment needed to perform a Foley catheterization, including a Foley catheter pre-connected to a drainage bag via tubing. Disston discloses a tray with "a pre-assembled catheter-tube- bag assembly contained therein," including a Foley catheter 7, drainage tube 8… and drainage bag 10." (Ex. 1008, 1:11-12, 2:15-23, Fig. 1.) The kit also includes equipment such as an underpad, sterile gloves, lubricant, and a water-filled syringe for inflation of the balloon on the Foley catheter. (Ex. 1008 at 2:15-26; Fig. 1.) The tray of Disston is sealed in a plastic bag ("a plastic outer envelope.") (Ex. 1008 at 2:24-28.)

89. Figure 1 of Disston shows the closed-system Foley catheter of Disston including Foley catheter 7 connected to drainage bag 10 via drainage tubing 8 all provided in a single layer tray 2. The inflation syringe 11 is also shown in Figure 1. (Ex. 1008 at 1:13-16, 1:59-67.)

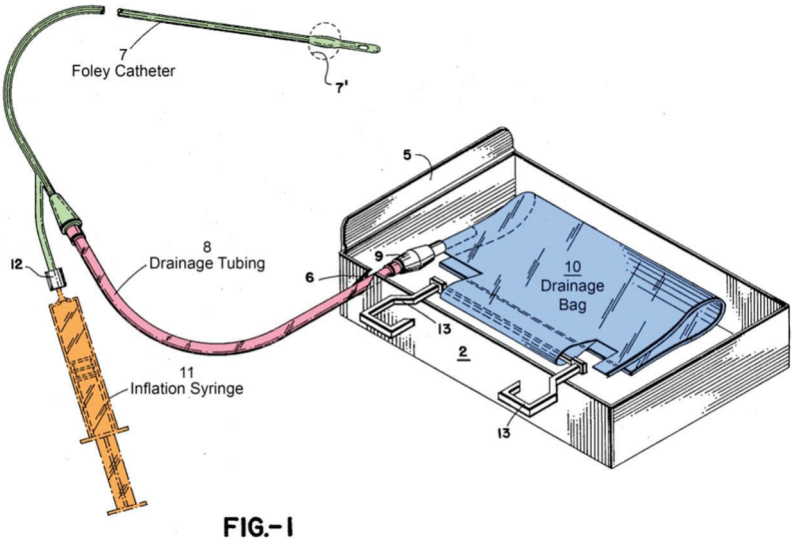


FIG.-1

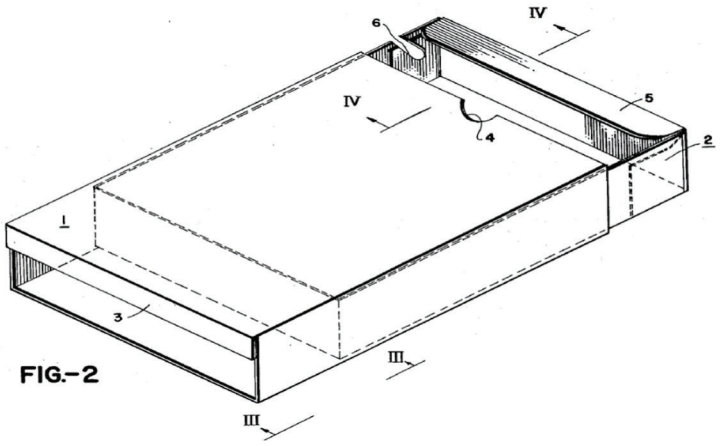


FIG.-2

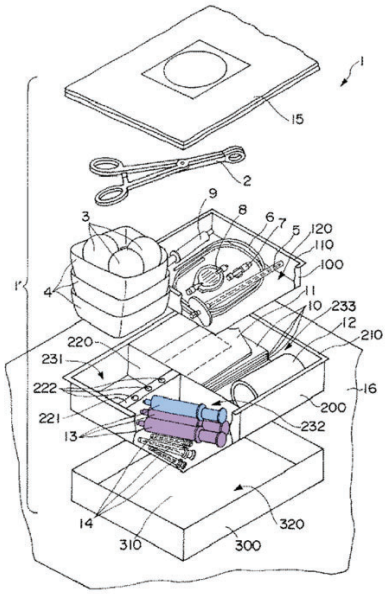
90. When opened, the tray of Disston presents contents including gloves, cleansing solution, protective pad or sheet, lubricant, sterile water packet, syringe, "and most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately." (Ex. 1008 at 1:26-35, 2:41-52, Figs. 1-2.)

E. Japanese Patent Application Publication No. 2007-229520 to Imai ("Imai")

91. I understand that Japanese Patent Application Publication No. 2007-229520 pertains to an application filed by Masaomi Imai. (Ex. 1011.) In this declaration, I rely on a certified translation of Imai. (Ex. 1012.) As indicated on the face of the Imai patent application publication, the application published on September 13, 2007.

92. I understand that, because Imai published on September 13, 2007, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

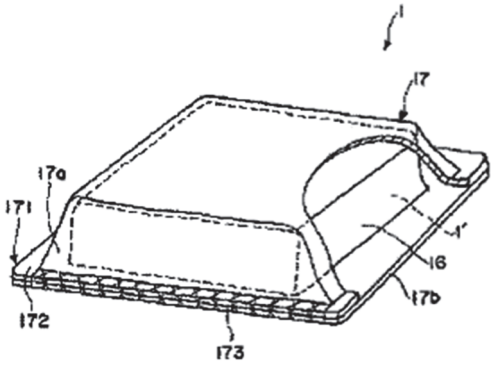
93. As seen in annotated Figure 1 below, Imai discloses a catheter kit, including a multi-compartmented single layer catheter tray 200 that stores equipment of the kit, such as syringes 12 in a first compartment (232), a catheter in a second compartment (233), and cotton balls in a third compartment (231). (Ex. 1012 ¶ 0015.) Imai also teaches that the syringes are stacked together in the same compartment. (Ex. 1012, ¶ 0014; Fig. 1.)



94. Tray 200 of Imai can be made out various materials such as plastics or paper: "Examples of the material utilized to constitute large tray 300, first small tray 100, and second small tray 200 (to be described later) include paper and different types of resins such as polyvinyl chloride, polyethylene, polypropylene, polystyrene, poly -(4- methylpentene -1), polycarbonate, acrylic resins, acrylonitrile- butadiene - styrene copolymers, polyesters such as polyethylene terephthalate, butadienestyrene copolymers, polyamide, and the like." (Ex. 1012 ¶ 0017.)

95. The tray of Imai includes an outer packing 17 and a wrap 16 around the tray.) Specifically, Imai discloses that "the entire kit body 1' is wrapped with one sheet 16, and further housed by packaging material 17 in a sealed manner." (Ex. 1012 ¶ 0064.) Imai includes components such as syringe 13, drape 15, epidural catheter 6, and connector 7. (Ex. 1012 ¶ 0014.)

[Figure 2]



96. Imai discloses that the packaging material 17 "is sealed by means of fusing (heat fusion, high frequency fusion, ultrasonic fusion, etc.) or adhesion (adhesion by an adhesive or a solvent)." (Ex. 1012 ¶ 0065.) Imai further describes that the packing material 17 and sheet 16 are formed using "materials with gas permeability and heat resistance that are compatible with sterilization, or materials that are capable of maintaining sterility after sterilization." (Ex. 1012 ¶ 0068.) Finally, Imai discloses that "the internal sterile state is securely maintained until packaging material 17 is opened." (Ex. 1012 ¶ 0070.)

97. **U.S. Patent No. 5,931,303 to Salvadori ("Salvadori")**

98. I understand that U.S. Patent No. 5,931,303 was issued to Lawrence A. Salvadori. As indicated on the face of the patent, it issued on August 3, 1999. (Ex. 1013.)

99. I understand that, because Salvadori issued on August 3, 1999, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

100. Salvadori discloses a urethral catheter kit wrapped in a "CSR wrap" wrap "to provide a barrier to gross contamination." (Ex. 1013 at 1:10-40.) "The kit includes an underpad, gloves, a fenestrated drape, lubricating gel, swab sticks, a catheter, and a collection bag. "The kit is typically called a tray, because the components are supplied in a tray-like device." (Ex. 1013 at 1:14-21.) "Swab sticks 60" are shown in annotated Figure 1 below:

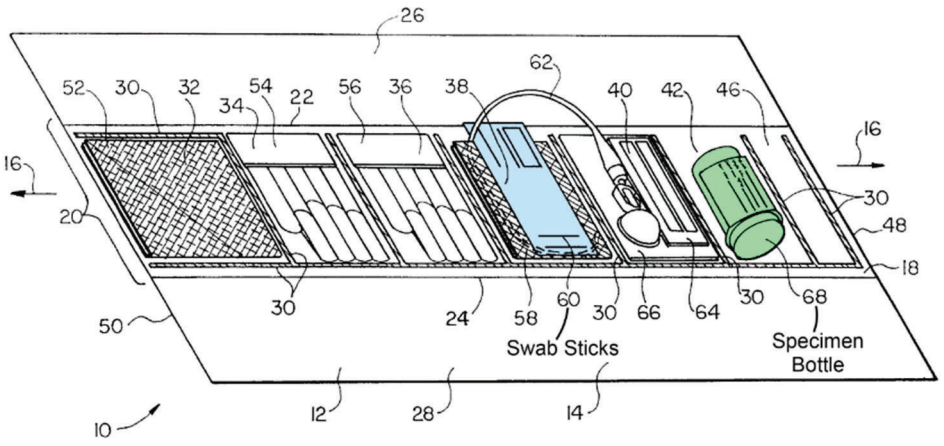


FIG. 1

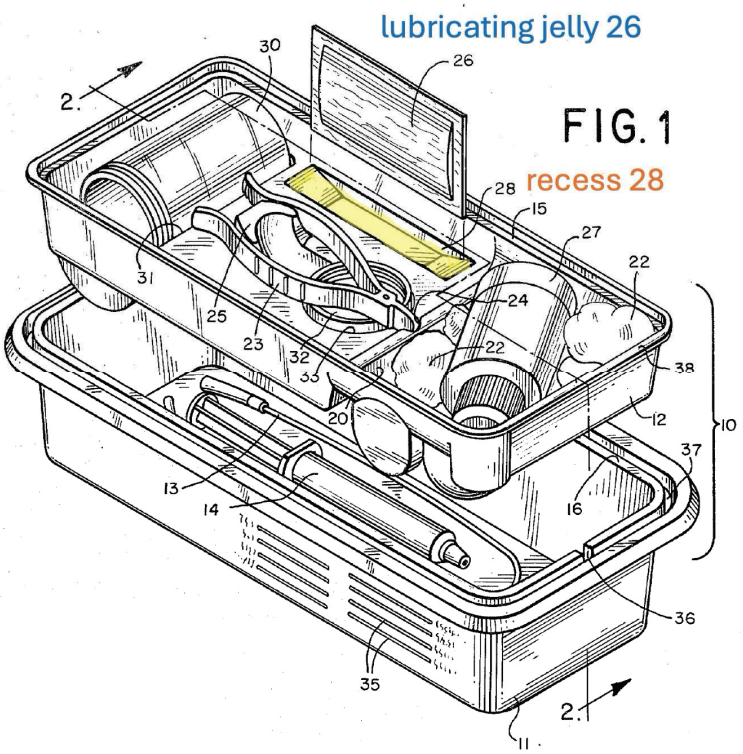
(Ex. 1013 at Fig. 1; 3:3-4.)

F. U.S. Patent No. 4,226,328 to Beddow ("Beddow")

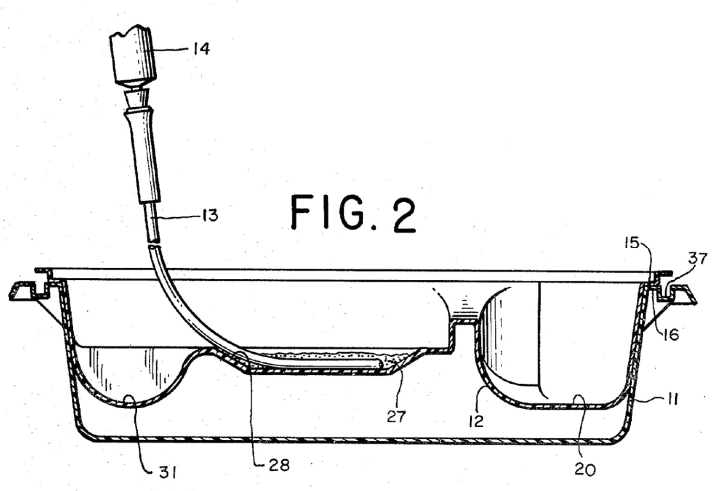
101. I understand that U.S. Patent No. 4,226,328 was issued to David V. Beddow. As indicated on the face of the patent, it issued on October 7, 1980. (Ex. 1010.)

102. I understand that, because Beddow issued on October 7, 1980, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

103. Beddow discloses a "single-use disposable catheterization package." (Ex. 1010 at Abstract.) Specifically, Beddow discloses a urethral catheterization tray with common urethral catheterization equipment, such as a urethral catheter 13, syringe 14, cleansing solution 21, balls 22, forceps 23, a lubricating jelly 27, and specimen bottle 30, as well as gloves, an underpad, and a drape stored in a tray. (Ex. 1010 at 2:41-3:30, Fig. 1.) As shown in Figure 1 of Beddow, the lubricating jelly is stored in recess 28 (a first compartment of the tray) where the lubricant is also dispensed. (Ex. 1010 at 3:11-16)



104. The urethral catheter of Beddow is then passed into recess 28 to lubricate the catheter as shown in Figure 2:



(Ex. 1010 at 3:18-22; Fig. 2)

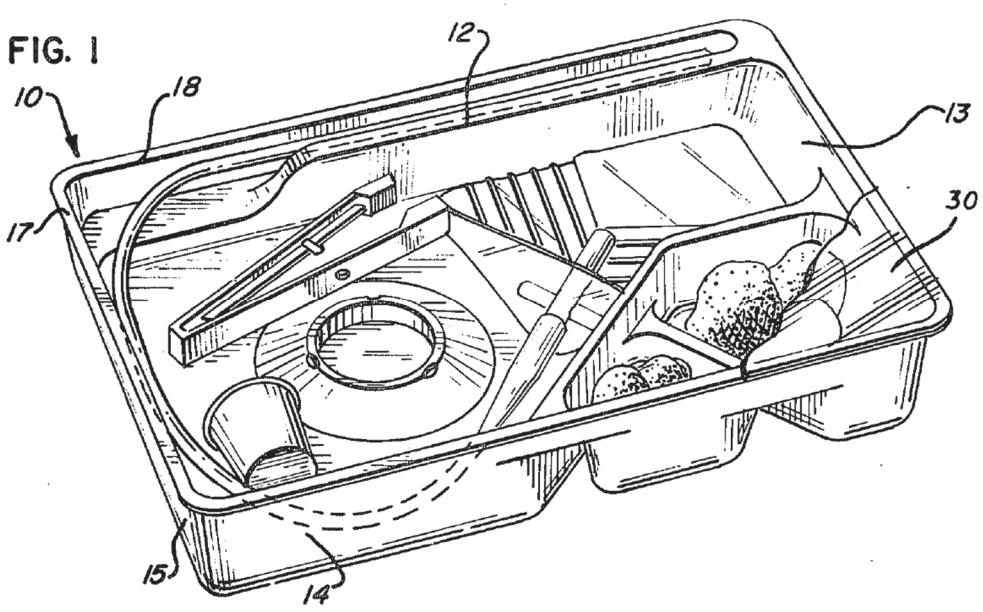
105. Beddow includes a wrap folded around tray between the tray and the outer "pouch." (Ex. 1010 at 2:34-50.) The outer pouch, which "may be formed of a transparent and flexible plastic film," "is sealed to maintain the sterility of the components within the catheterization package." (Ex. 1010 at 2:34-50.)

G. U.S. Patent No. 4,160,505 to Rauschenberger ("Rauschenberger")

106. I understand that U.S. Patent No. 4,160,505 was issued to Richard A. Rauschenberger. As indicated on the face of the patent, it issued on July 10, 1979. (Ex. 1021.)

107. I understand that, because Rauschenberger issued on July 10, 1979, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

108. Rauschenberger discloses a single layer urethral catheter tray design. (Ex. 1021 at Figs. 1-3.) The tray of Rauschenberger includes multiple compartments as shown in Figures 1 and 2 below, such as lubrication channel 21, a main compartment the stores at least the drainage bag and a portion of the attached urethral catheter, forceps, and specimen cup, and compartments 23 and 24 that store absorbent pads. (Ex. 1021 at 1:50-2:45.) Figure 1 of Rauschenberger below shows the catheter pre-attached to a drainage bag:

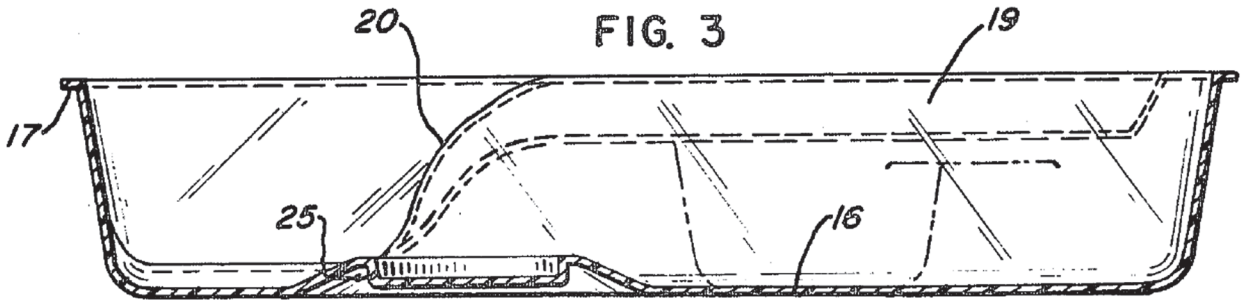


109. Rauschenberger notes that prior art trays (i.e., trays from before 1977) included CSR wraps and that steps of the catheterization procedure were performed on the CSR wrap such as the lubrication of the catheter and the application of antiseptic solution to pads. (Ex. 1021 at 1:8-26.) Rauschenberger notes that using

the CSR to perform these steps is "less than ideal" because "inadvertent movement by the patient could contaminate the sterile work area" and "[d]uring the procedure lubricant jelly, antiseptic solution, and wet absorbent pads are placed on the CSR wrap, where they can be contacted either by the patient or the attending personnel." (Ex. 1021 at 1:29-43.) Thus, Rauschenberger provides a single layer tray with multiple compartments where the compartments function to allow these steps to be performed within the sterile surface of the tray. For example, Rauschenberger includes a lubrication channel 21 that is formed from inset wall 12 and perimeter wall 18 that allows the clinician to lubricate the catheter within a compartment of the tray. (Ex. 1021 at 1:59-61, 2:28-2:42.) Specifically, the lubrication channel "is adapted to receive a conventional urethral catheter." (Ex. 1021 at 1:62-63.) The tray also includes contouring to hold components in place, such as recess 26, which is sized to "receive and stabilize" the urine specimen container. (Ex. 1021 at 2:55-63.)

110. Rauschenberger discloses arranging its equipment from top to bottom in its order of use: "The remaining components generally are arranged sequentially from the top of the tray on down in the order: gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container. For purposes of clarity, not all of the components are shown in the drawings." (Ex. 1021 at 2:22-27.) This is the same order in which Rauschenberger discloses removing this equipment from the tray and using it. (Ex. 1021 at 2:28-2:63.)

111. Figure 3 of Rauschenberger shows another perspective of the tray:



H. Nursing Standard Article

112. A Nursing Standard Article entitled "Reducing the risks associated with urinary catheters," published on March 25, 2009 ("Nursing Standard"), describes the procedure for using an "all-in-one Foley tray." (Ex. 1019 at 52-53.)

113. I understand that Nursing Standard published before the June 3, 2009 priority date to which Medline contends it is entitled, so it is prior art under pre-AIA 35 U.S.C. § 102(a).

114. I have seen no evidence that the '219 patent is entitled to an earlier priority date than the date of its patent application. To the extent Medline were to attempt to swear behind Nursing Standard, it would not change any of my opinions in my report. First, Nursing Standard is not explicitly used as part of the Grounds of any combination. Second, I cite Nursing Standard to show what a POSA would have known at the time of the invention, such as that a closed-system Foley catheter reduces the risk of CAUTI. (Ex. 1019 at 51.) Such teachings are relevant regardless of whether Medline could swear behind Nursing Standard. For example, Nursing

Standard cites to an article from 1964 in support of the fact that closed-systems reduce CAUTI. Indeed, Bard's closed-system Foley catheter patent to Serany was filed in 1965 and notes that "[a]nother object of this invention is to provide a catheterization package which reduces the incidence of infection." (Ex. 1009 at 1:31-32.) Thus, Nursing Standard's disclosure is merely corroborative of Serany's teaching, which preceded the '219 patent by several decades. Additionally, I note that Nursing Standard describes an "all-in-one Foley tray" but as stated in Nursing Standard, the "urinary catheter kit is a new concept for the UK but **has been in use in the United States (US) and elsewhere for a number of years**," which I can personally confirm based on my work in investing these kits when developing a urinary catheter in the 2007 to 2009 timeframe. (Ex. 1019 at 52 (emphasis added).) Thus, even if Medline could swear behind Nursing Standard, its teachings are relevant as to what a POSA would have understood both at and before the time of the invention.

115. The Nursing Standard describes an "all-in-one Foley tray" with "commonly used products" that have been available in the U.S. for a number of years:

116. Bard has developed an all-in-one Foley tray, which incorporates the equipment needed for urinary catheterization (Box 1). This system is a new concept for the UK but has been in use in the United States (US) and elsewhere for a number of years. The Foley tray contains commonly used products. A range of catheter

materials, sizes and lengths are available. It is hoped that, by accessing a single pack rather than several items, healthcare professionals' speed and efficiency will be optimized. (Ex. 1019 at 52; Figure 1.)

FIGURE 1

Pre-connected system



117. Nursing Standard further lists the contents of an "all-in- one Foley tray":

BOX 1

Contents of an all-in-one Foley tray

- Two pairs of latex-free gloves.
- Apron.
- Rubbish bag.
- Waterproof surface blanket.
- Sterile field/patient protection fenestrated drape.
- Vial 0.9% sodium chloride solution.
- Five gauze swabs.
- 10ml prefilled syringe of sterile water.
- 10ml syringe.
- Syringe of urethral lubricant.
- Foley catheter stabilisation device.
- Pre-connected catheter and drainage bag (choice of catheters and drainage bags).

(Ex. 1019 at 52.)

118. Nursing Standard notes that an all-in-one Foley tray includes a "pre-connected catheter and drainage bag," which it notes is a "closed system." (Ex. 1019 at 52.) It states: "Catheters should be connected to a sterile catheter bag or valve, creating a closed system." (Ex. 1019 at 52.) The article emphasizes the importance of a "closed system" catheter in reducing catheter-associated urinary tract infections ("CAUTIs"). Specifically, the article explains that CAUTIs drop by over 80% when using a closed system, as disclosed in the above references. (Ex. 1019 at 51.)

I. Male Catheter Insertion YouTube Video ("Catheterization Video")

119. The Nursing Lab: Take Two *Male Catheter Insertion* video was uploaded to YouTube on February 7, 2008 by user "sterilefield" and currently has 1,700,400 views as of December 23, 2024 ("Catheterization Video"). (Ex. 1020.) https://youtu.be/ISBAya_5cIM.

120. I understand that the Catheterization Video was published (i.e., uploaded publicly on the YouTube website) more than one year before the June 3, 2009 priority date to which Medline contends it is entitled, so it is prior art under pre-AIA 35 U.S.C. § 102(b).

121. The Catheterization Video is a training video that has a clinician narrate and demonstrate the steps of performing a Foley catheterization using an all-in-one Foley catheter kit.

122. The Catheterization Video teaches the common practice (also taught by Beddow as discussed above) of lubricating the catheter where the lubricant is stored. Specifically, at 2:43 to 2:50 of the video, the healthcare provider picks a lubricant-filled syringe out of the tray and squirts lubricant into a compartment of the tray. (Ex. 1020.) The Catheterization Video thus also shows that it was well-known to include lubricant in a lubricant syringe.



123. The clinician says while performing this operation that "I'm going to squirt my lube into this little container where the syringe was." (Ex. 1020 at 2:43-2:60.) Subsequently, the clinician lubricates the catheter in the compartment that previously held the lubricant syringe and where the lubricating jelly was dispensed.



(Ex. 1020 at 4:50 to 4:55.)

124. After the Foley catheter is inserted, the clinician inflates the retention balloon with sterile water from the inflation syringe, which attached to the inflation port of the Foley catheter:



(Ex. 1020 at 5:35.)

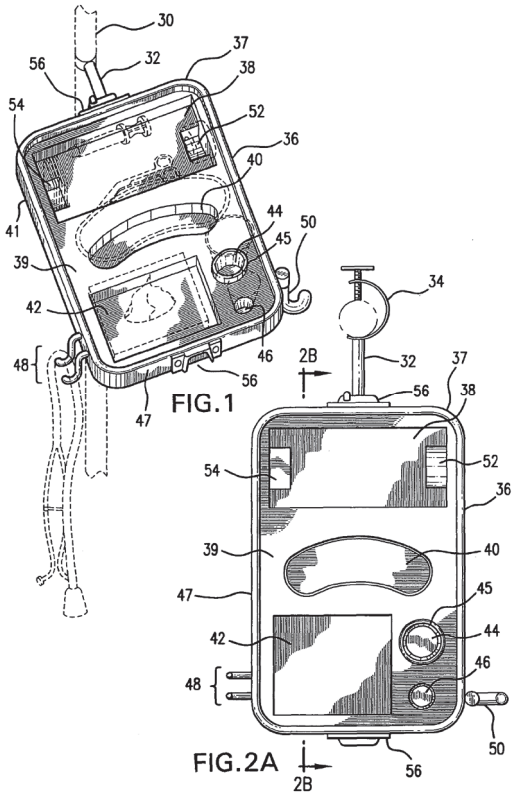
125. Accordingly, the Catheterization Video further shows that it was common to include two syringes in Foley catheter kits (to lubricate the catheter and inflate the retention balloon) more than one year before June 3, 2009.

J. U.S. Patent No. 7,967,137 to Fulbrook ("Fulbrook")

126. I understand that U.S. Patent No. 7,967,137 was issued to Jason D. Fulbrook. As indicated on the face of the patent, it was filed on June 9, 2008 and issued on June 28, 2011. (Ex. 1029.)

127. I understand that, because Fulbrook was filed more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(e). This U.S. patent was also not a listed cited reference during the prosecution of the '219 patent.

128. Fulbrook discloses a "tray organizer" for "organizing routine expendable medical supplies … with shaped recessed for retaining medical supplies." (Ex. 1029 at Abstract; Fig. 1 and 2A.) The tray of Fulbrook is a single layer tray as shown in the Figures below:



129. The tray is "made from … injection molded plastic… with a plurality of profiled recesses for receiving expendable medical supplies." (Ex. 1029 at Abstract; 5:50-53; Figs. 1-5.)) Specifically, Fulbrook discloses: "The organizer tray itself will be composed of an injection molded composite material." (Ex. 1029 at 3:61-62.) "As stated, the organizer tray will preferably be produced from an

injection mold and will be composed of a composite material that is resistant to high temperatures and cleaning solvents, and which offers a high durability. (Ex. 1029 at 11:61-64.) As shown in Figure 1, Fulbrook includes "[r]ectangular shaped recessed openings for securing appliances such as **syringes**, scissors, and re-usable supplies such as surgical tapes, and other miscellaneous items." (Ex. 1029 at 13:12-15.) Fulbrook also notes that "shaped recesses include the capability to accommodate a plurality of shapes" and "provide upstanding rims capable of securing different shaped items." (Ex. 1029 at 15:8-12.) A POSA would have understood that Fulbrook's injection molded tray with a plurality of compartments (i.e., "recesses for receiving expendable medical supplies") are made from a single surface. (Ex. 1029 at Figs. 1-5, Abstract; 5:50-53.)

K. U.S. Patent No. 6,158,437 to Vagley ("Vagley)

130. I understand that U.S. Patent No. 6,158,437 was issued to Richard T. Vagley. As indicated on the face of the patent, it issued on December 12, 2000. I understand that, because Vagley issued on October 7, 1980, more than one year prior to the earliest alleged priority date of the '219 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

131. Vagley discloses a "surgical tray" provided with surgical instruments. (Ex. 1027 at 1:11-19; 2:18-24, Fig. 1.) Within the tray, Vagley discloses "positioning instruments sequentially in the order in which they will be employed

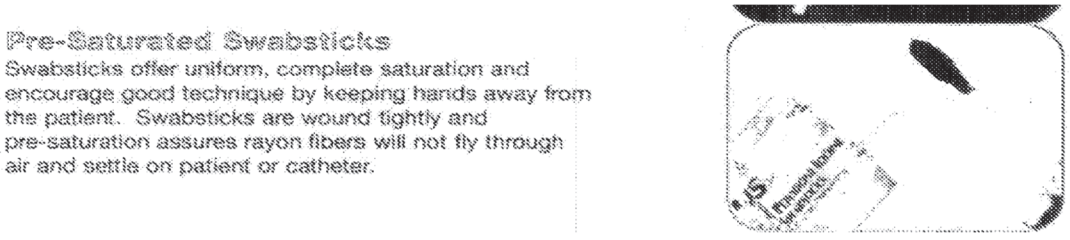
for a particular surgical procedure." (Ex. 1027 at 4:26-28; Fig. 1.) In particular, Vagley discloses that "eight instruments will be employed in a sequence going from left to right" and that "in the sequence refers to the individual instruments being used by the surgeon in a specific surgical procedure starting from the left and going to the right." (Vagley at 3:15-25.) Thus, Vagley illustrates that when arranging medical instruments in a tray in their order of use it was known to arrange them from left-to-right.

L. Medline's Better by Design Brochure ("Medline Brochure)

132. I understand that Medline submitted a "Medline Urological Better By Design" brochure during the prosecution of Patent Application No. 12/945,148, to which I understand the '220 patent claims priority, in an IDS. (Ex. 1024 at 0005.) The document called "Medline Aritcle[sic.]Brochure" was identified as Non Patent Literature and as being published in 2008. Thus, I understand that Medline brochure was published before June 3, 2009 priority date so it is prior art under at least pre-AIA 35 U.S.C. § 102(a).

133. The Medline brochure describes "Closed System Foley Trays" and notes that a Medline Foley tray includes "swabsticks": "The Medline Prep Tray includes… Aloetouch 3G latex-free wrapped gloves, 3PVP swabsticks, underpad, fenestrated drape, prefilled inflation syringe, lubricant syringe, specimen container w/ ID label." (Ex. 1024 (Medline Brochure) at 0015 (emphasis added).) A POSA

would understand that "3PVP" means three povidone-iodine swabsticks. Povidone-iodine is a cleansing material that is pre-applied to the swabsticks. I am familiar with these swabsticks because, as noted above, I did work on urinary catheter development during this timeframe (from 2007 to 2009). In particular, I am familiar with their dimensions, which I understand to be typical of swabsticks that were available in urinary catheter kits before 2009. The brochure also mentions the benefits of the "Pre-Saturated Swabsticks" provided in Foley catheter kits as compared to rayon fibers (which is a reference to rayon balls – a different solution that serves the same purpose, i.e., used to clean the patient's genitals)):



(Ex. 1024 at 0007.)

X. GROUNDS

A. Identification of Grounds

134. The following grounds are presented below.

Ground	35 U.S.C. §[1]	Claims	Prior Art References
1	103(a)	1, 3-7, 9-14	Numata, Serany, Disston, and Beddow

[1] The pre-AIA version of 35 U.S.C. §§ 102 and 103 applies to the Challenged Claims.

2	103(a)	2	Numata, Serany, Disston, and Beddow, and Salvadori
3	103(a)	15-16	Numata, Serany, Disston, Beddow, Salvadori, and Imai
4	103(a)	13-14	Rauschenberger, Serany
5	103(a)	15-16	Rauschenberger, Serany, Salvadori
6	103(a)	13-14	Solazzo, Serany, Disston, and Imai
7	103(a)	15-16	Solazzo, Serany, Disston, Imai, Salvadori

B. Ground 1: Obviousness Over Numata, Serany, Disston, and Beddow (Claims 1, 3-7, 9-13)

1. Independent Claim 13

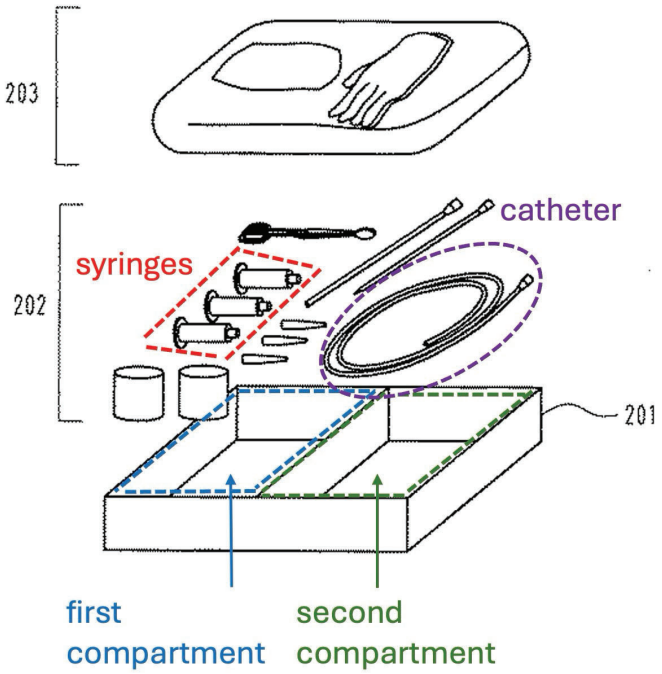
(a) Limitations 13[p] and 13[a]

135. Numata discloses "*A medical procedure kit, comprising: a first syringe and a second syringe*."

136. Numata discloses a medical procedure kit: "a package body for storing medical instruments for use in surgical procedures for diagnosis, treatment, etc., employing disposable medical instruments such as catheters." (Ex. 1007 ¶ 0001.) "[T]he instruments to be used for a catheter procedure are packaged together in **a single tray**" in order "to reduce the effort of purchasing and arrangement and prevent usage errors and preparation errors." (Ex. 1007 ¶¶ 0005 (emphasis added); Figure 4.) Numata therefore teaches the storage of medical equipment such as a catheter and syringes in a single layer tray to help prevent errors and maintain aseptic technique.

137. Numata thus discloses "a single layer tray," and the tray has multiple compartments (including a first compartment for storing a first syringe and second syringe) as shown in annotated Figure 4 below:

(FIG. 4)



(Ex. 1007 at Fig. 4; ¶ 0003.)

138. The description of Figure 4 in Numata states that "FIG. 4 and FIG. 5 are drawings explaining the configuration of the medical product 200" and "[a]s shown in Figure 4, "the medical product storage pack 100 stores medical instruments 202 such as **catheters**, **syringes**, injection needles, forceps and degreasing cotton," (Ex. 1007 at Fig 4; ¶ 0031 (emphasis added).) A POSA would understand based on the depiction of the items in Figure 4 and the accompanying description that the "single tray" of Numata stores three syringes in a left compartment and a catheter in

a right compartment. Although the items in Figure 4 are not labelled, the syringes are easily identifiable to a POSA because of their cylindrical shape along with the flange at one end and tip at the other end. The catheter is also easily identifiable to a POSA because a catheter is generally a long, hollow tube and often are coiled to fit with the confines of the kit as shown in Figure 4.

139. Given the configuration of equipment shown in Figure 4 of Numata, Numata discloses a first compartment (on the left) for receiving syringes and a second compartment (on the right) for receiving a medical assembly (a coiled catheter) as shown Figure 4 above.

140. Accordingly, Numata discloses this claim element.

(b) Limitation 13[b]

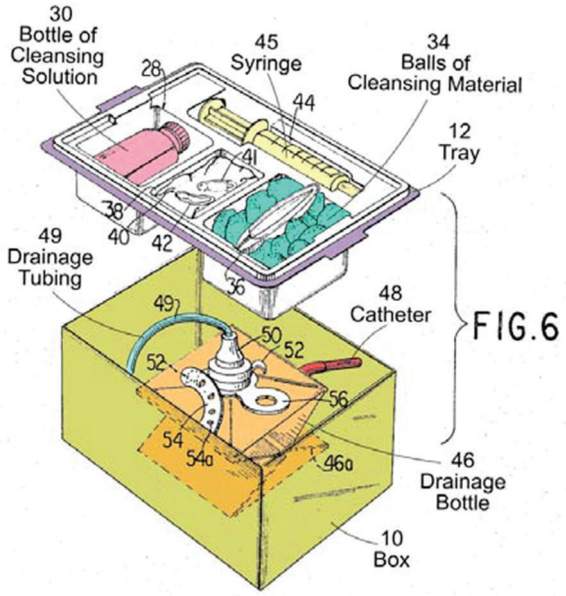
141. Numata in view of Serany and Disston discloses "*a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*."

142. For the reasons at limitation 13[a], Numata discloses a medical assembly (a catheter) in a second compartment. (Ex. 1007, Fig. 4; ¶ 0031.) As discussed below, Serany and Disston disclose "*the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter*," i.e., a closed-system Foley catheter. It would have been obvious in view of Serany and/or Disston to add Foley catheter equipment, including a closed-system Foley catheter, to the kit of Numata. And it would have further been obvious to a POSA to place the closed-

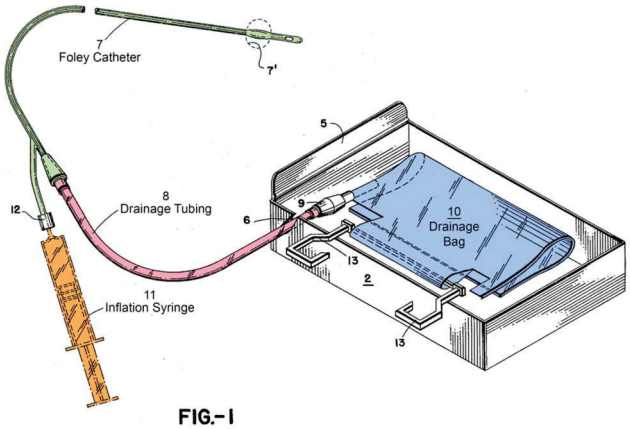
system Foley in the second compartment of Numata, to replace the catheter that is depicted in Figure 4. The second compartment of Numata has ample room to house a closed-system Foley catheter, and placing it in the second compartment would separate it from the other equipment stored in the kit (e.g., syringes), thereby protecting it from damage.

143. The packaging invention of Numata can be employed to store various types of medical equipment, and therefore is broadly directed to a "package body for storing medical instruments" for procedures "employing disposable medical instruments such as catheters." (Ex. 1009 ¶ 0001.) The exemplary embodiment of Numata is a kit that stores "medical instruments used for surgery, such as catheters for introduction into blood vessels and their accessories." (Ex. 1004 ¶ 0037.) "However, the invention is also applicable to any other medical products . . . which are sold sealed within packaging material in a sterilized state." (Ex. 1004 ¶ 0037.)

144. A closed-system Foley catheter (i.e., a Foley catheter pre-attached to a drainage bag) is a medical product that is sold sealed within packaging material in a sterilized state. Serany discloses a sterilized medical device kit were "[e]verything is available in the proper order of use and in sterile condition," which thus includes the closed-system Foley catheter of Serany (i.e., "a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use." (Ex. 1009 at 1:23-25; 3:23-26.)



145. Although Serany refers to the catheter as being connected to a "drainage bottle," it describes the "bottle" as being made out of a "flexible plastic material" that can be collapsed inside the box. (Ex. 1009 at 3:26-32; Fig. 6.) A POSA would understand Serany to therefore teach a fluid bag because a collapsible drainage receptacle made of a flexible plastic material could also be considered a bag. To the extent Medline argues that Serany does not teach a bag, it would have further been obvious to substitute the "bottle" of Serany with a "bag." Fluid bags were well-known in the art. For example, Disston teaches a Foley catheter 7 attached to a "drainage bag 10" as shown in annotated Fig. 1 below:



(Ex. 1008 at Fig. 1; 2:19-23.) Doing so would merely involve a simple substitution of one container (a "bottle") for another known type of container (a "bag") to produce predictable results.

146. In view of Serany and Disston, it would have been obvious to add a closed-system Foley catheter the tray of Numata. This is a simple substitution of a known element (the catheter of Numata) with another (the closed system Foley catheter of Serany/Disston). A POSA would have been motivated to do so as set forth below.

147. First, Numata makes clear that its "invention is also applicable to **any other medical products** . . . which are sold **sealed within packaging material in a sterilized state**." (Ex. 1007 ¶ 0037 (emphasis added).) Numata's invention therefore applies to Foley catheters, which are sold in a sterilized state. Serany discloses a kit sold in a sealed, sterilized state: "From the above description it will

be seen that all the components to effect catheterization **have been provided in a compact, sealed, and sterile package** ready for use in the order needed." (Ex. 1009 at 3:63-4:2 (emphasis added).) Serany also discloses: "The components are maintained sterile until the package is opened" and that "[e]verything is available in the proper order of use and in sterile condition. (Ex. 1009 at 1:12-16; 1:23-25) Disston also discloses "a sealed sterile package." (Ex. 1008 at 1:26-27.) This is a simple substitution of one known element (catheters for introduction into blood vessels) for another (a Foley catheter system) to obtain predictable results (customizing the equipment of Numata to allow the performance of a different medical procedure while utilizing the packaging invention of Numata).

148. Second, while Serany stores its equipment in multiple trays, Numata discloses "the instruments to be used for a catheter procedure are packaged together in a single tray" to "prevent **usage errors** and **preparation errors**." (Ex. 1007 ¶ 0005 (emphasis added).) These are the same reasons the '219 patent provided (albeit many years after Numata) for storing its equipment in a single container:

> Prior art systems, for example such as those in which the catheterization procedure components are shipped in separate containers, may contribute to substandard techniques in that the catheter can become contaminated when moving it from its shipping container. Consequently, the patient can be at an elevated risk of infection as the catheter is moved from one tray to another. Embodiments of the present invention solve this problem by providing a single level tray 100 with compartments.

. . .

> By having easy access to the components disposed in the single level tray 100, the medical services provider can more **easily prepare and use the components** within the tray 100. This helps to minimize the risk of contaminating the patient or the sterile field during the procedure.

(Ex. 1001 at 7:54-8:2 (emphasis added).)

149. Thus, based on the teachings of Numata, a POSA would have been motivated to use the single tray of Numata to accommodate Foley catheter equipment to "prevent usage errors and preparation errors."

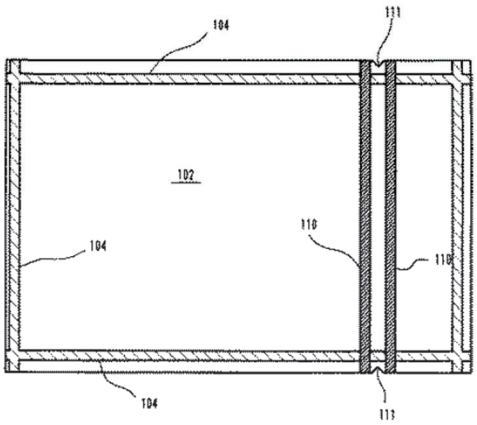
150. Third, a POSA would have been motivated to add Foley catheter equipment (such as a catheter attached to fluid bag) to the kit of Numata because several pieces of equipment stored in the kit Numata, such as syringes, gloves, cotton balls and forceps, and drapes were also commonly included in Foley catheter kits. (Ex. 1007 ¶ 0037, Fig 4; Ex. 1009 at 2:21-3:45, Fig. 6; Ex. 1008 at 2:15-72, Fig. 1.) Thus, a POSA would understand that the kit of Numata is particularly well-suited for use with a Foley catheter.

151. Fourth, a POSA would have been motivated to add Foley catheter equipment (such as a catheter attached to fluid bag) to the kit of Numata to utilize the packaging invention of Numata. Numata notes that "disposable medical instruments" are employed "to reduce the risk of nosocomial infections." (Ex. 1007

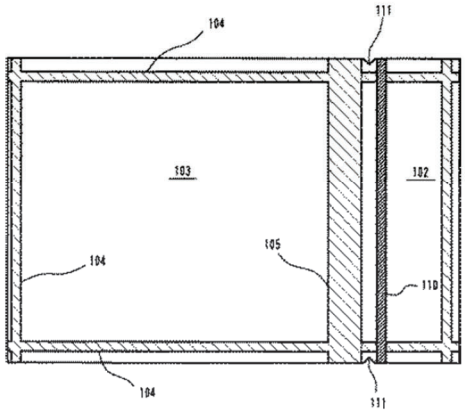
¶ 0002.) Specifically, Numata's invention is designed to eliminate or reduce the risk of contamination via the outside of the outer packaging.

152. Specifically, as discussed in Section IX.2 above, Numata's kit allows for the removal of the medical instruments from the packaging bag without touching them. (Ex. 1007 ¶ 0009.) As shown in Figures 1 and 3 below, Numata discloses a packaging bag with a notch 111 and a tape [110] forming a cut line along the notch." (Ex. 1007 ¶ 0020.)

(FIG. 1)

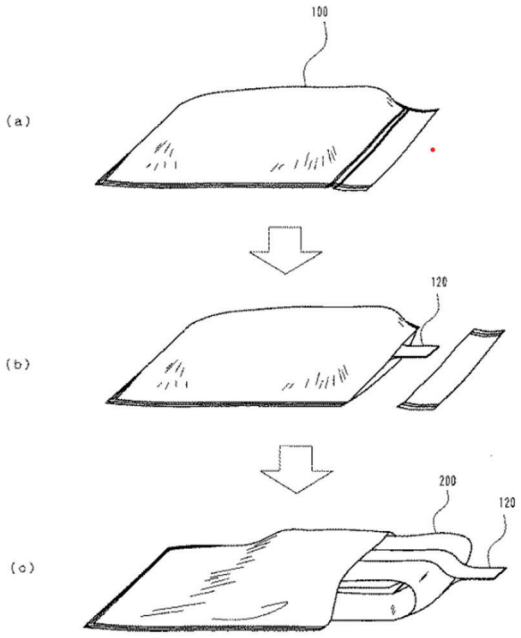


(FIG. 3)



153. By "cutting off the end of the medical product storage pack 100 from the notch 111," "the end of band 120" is exposed as shown in Figure 7(b).

(FIG. 7)



(Ex. 1007 ¶ 0036; Fig. 7.) The medical product 200 can then be removed from the packaging bag by "pulling the band 120." (Ex. 1007 ¶ 0036.) With this operation, medical product 200 can be removed without the need to "directly touch[] the medical product 200 with one's hands" thus reducing the risk of contamination and thereby the risk of infection. (Ex. 1007 ¶ 0036.)

154. Thus, a POSA would have been further motivated to add Foley catheter equipment to Numata's single tray to utilize Numata's packaging solution (i.e., its outer bag, wrap, and band) to perform Foley catheterization procedures to reduce the risk of contamination and infection.

155. Finally, there would be a reasonable expectation of success in combining Numata with the sterile catheter equipment of Serany and/or Disston.

Numata, Serany, and Disston each provide a medical procedure kit with sterile equipment. (Ex. 1007 ¶ 0037; Ex. 1009 at 3:63-4:2; Ex. 1008 at 1:26-27.) Each kit includes similar equipment (such as catheters, syringe, forceps, cotton, gloves, and drapes). (Ex. 1007 ¶ 0037, Fig 4; Ex. 1009 at 2:21-3:45, Fig. 6; Ex. 1008 at 2:15-72, Fig. 1.) Numata and Serany both provide a wrap and bag around the tray. (Ex. 1007 at Fig. 6-7; Ex. 1008 at Figs. 1-5.) Disston also seals its equipment with an outer envelope. (Ex. 1008 at 2:29.)

156. Numata provides the following dimensions:

> A medical product storage pack 100 of the present invention was created with the following dimensions:
>
> Medical product storage pack 100: 600 mm × 850 mm
>
> Synthetic resin sheet 102: 600 mm × 1,000 mm (with 150 mm at the end folded back)
>
> Gas-permeable sheet 103: 600 mm × 700 mm
>
> Band 200: 30 mm × 1,700 mm

(Ex. 1009 ¶ 0039.)

157. I note that the dimensions of the tray itself are not expressly provided but a POSA would understand based on the Figures and basic packaging principles that the size of the tray would be similar to the size of the outer packaging (i.e., a bit smaller to fit within the package but not significantly smaller as that would impact the ability of the packaging to hold the equipment in place as well as be needlessly wasteful).

158. The medical storage pack has dimensions of approximately 600mm (23.62 inches) x 850 mm (33.46 inches), which is considerably larger than the dimensions required to accommodate a Foley catheter system. For example, the '219 patent discloses a tray width between nine and twelve inches (approximately 23 to 30 cm) and length between eight and eleven inches (approximately 20 cm to 28 cm), which is broadly typical of Foley catheter kits based on my development work with these products before 2009. (Ex. 1 at 4:51-58.) Thus, a POSA would understand that all of the Foley catheter equipment added to the kit could easily be accommodated within the dimensions of Numata, and the only possible work needed would be to modify the tray to be made smaller as it would be more efficient to store equipment in a tray that is just large enough to accommodate all of its equipment. This is a well-known and trivial modification to a POSA as sizing a tray to fit the equipment within is a basic principle in medical device packaging in order to prevent damage to the equipment and save resources (i.e., reduce shipping and manufacturing costs).

159. Thus, it would been obvious to customize the kit of Numata to fit the equipment within, such as by reducing the length and width of the tray. Although Numata does not provide a height for the tray, it would have been obvious for the tray to have a height of approximately two to three inches (approximately 5 cm to 7.5 cm), which would easily be sufficient to accommodate Foley catheter equipment.

This applies a known technique (sizing a tray to fit the components within) to a known device (a catheter kit) to yield predictable results.

160. Accordingly, Numata in view of Serany and Disston discloses this claim element.

(c) Limitation 13[c]

161. For the reasons at limitation 13[a], Numata discloses "*a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembl*y." (Ex. 1007 at Fig. 4; ¶¶ 0003, 0031.)

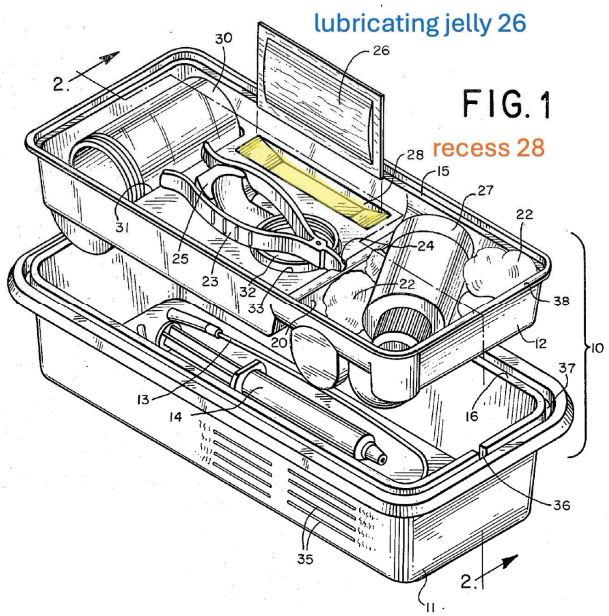
(d) Limitation 13[d]

162. Claim 13[d] requires "*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber*." Numata in view of Beddow discloses that the left compartment of Numata is a "*lubricating jelly application chamber*." Numata and Beddow also disclose "*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber*."

163. As discussed at claim 13[a] above and 13[f] below, Numata discloses multiple syringes in its first (or left) compartment and it would have been obvious to fill one of the syringes with lubricating jelly when customizing the kit of Numata to perform a Foley catheterization procedure.

164. Beddow discloses "*a lubricating jelly application chamber*" that *"allow[s] passage of at least some of the Foley catheter*" into the chamber. It was known in the art to lubricate the catheter in the compartment where the lubricant is stored in view of Beddow. Specifically, Beddow teaches using the compartment that stores the lubricant as a lubricating jelly application compartment to receive lubricating jelly: "To provide for lubrication of the catheter, the catheterization package 10 includes an individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28. In use, this container is removed from recess 27 [sic] and torn open, and the lubricating jelly contained therein is deposited in the recess." (Ex. 1010 at 3:11-16.)

165. As shown in Figure 1 of Beddow below, the lubricating jelly is stored in recess 28 (a first compartment of the tray) where the lubricant is also dispensed.



166. Once the lubricant is dispensed, the catheter is passed into the first compartment of Beddow (recess 28) to lubricate the catheter: "After the patient has been prepared, the catheter is lubricated with the lubricating jelly 27 by positioning the catheter tip in the jelly-filled recess 28, as shown in FIG. 2, and the catheterization procedure is carried out in a conventional manner." (Ex. 1010 at 3:18-22; Fig. 2.)

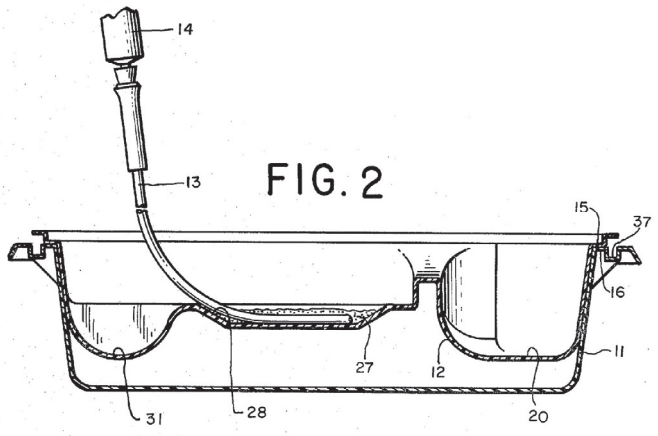


FIG. 2

167. In view of Beddow, a POSA would have been motivated to use the first compartment of Numata as a lubricating jelly application chamber because the first compartment would also store the lubricant, as discussed at 13[a] and [f]. This applies a known technique (the dual-use of a compartment to store lubricant and receive lubricant) to a known device (a catheter tray) ready for improvement to yield predictable results.

168. A POSA would also have recognized that the first compartment of Numata was well-suited to lubricate the catheter, and thus meets any functional and

structural limitations that this claim may require. As discussed below, (1) there is ample space to lubricate the catheter in the first compartment of Numata; (2) the compartment is easily accessible; (3) the first compartment has a smooth surface made of hard plastic to make it easy to run the catheter through the lubricant; and (4) the tray is sterile.

169. *First*, as discussed at claim 13[b], the medical storage pack has dimensions of approximately 600mm (23.62 inches) x 850 mm (33.46 inches). (Ex. 1009 ¶ 0039.) Dividing this in half as shown in Figure 4 means the first compartment of tray 200 would have dimensions of at least approximately 11 by 16 inches. This is plenty of room to lubricate the catheter. I note that the prior art describes lubricating the tip of the catheter. For example, Beddow states "After the patient has been prepared, the catheter is lubricated with the lubricating jelly 27 by positioning the catheter tip in the jelly-filled recess 28, as shown in FIG. 2." (Ex. 1010 at 3:18-21.) The '219 patent also describes lubricating the tip of the catheter: "Step 1509 also instructs the health care services provider to pass the tip of the catheter through the first opening in the wall separating the first compartment and second compartment into the lubricating jelly, thereby **lubricating the tip of the catheter**." (Ex. 1001 at 18:23-27 (emphasis added).) A POSA would therefore understand that only the tip of the catheter needs to be lubricated. However, I understand from Dr. Yun that it may be preferable in some instances to lubricate up

to around five inches of the catheter. (Ex. 1003 ¶ 135.) Numata's first compartment provides plenty of space to lubricate five inches of the catheter.

170. *Second*, Numata's second compartment (a lubricating jelly application compartment) is easily accessible because the tray has an open top and has a relatively minor depth (2 to 3 inches as discussed at limitation 13[c]). Also, as Numata notes, "the instruments to be used for a catheter procedure are packaged together in a single tray," which may "prevent usage errors and preparation errors." (Ex. 1007 ¶¶ 0005.) This means the catheter can be lubricated simply by passing the catheter over the internal wall from the second compartment to the adjacent first compartment, which is a trivial operation, and allows for the catheter to be lubricated while remaining within Numata's "single tray." By contrast, Beddow requires passing the catheter between two trays. (Ex. 1010 at Fig. 10.) Thus, a POSA would understand that Numata' medical procedure kit "*allow[s] passage of at least some of the Foley catheter into a lubricating jelly application chamber*."

171. *Third*, Numata's kit is "sold in a sterile state in a sealed packaging form" (Ex. 1007 ¶¶ 0030.) Thus, the second compartment of Numata provides a sterile surface in which to lubricate the catheter. *Fourth*, Numata's kit is made of a hard plastic, which a POSA would understand thus provides a smooth surface on which to lubricate the catheter. (Ex. 1007 ¶¶ 0031.)

172. Finally, Numata only teaches two compartments. Thus, it would have been obvious to try using the first compartment as a lubrication compartment given the finite number of options where the catheter could be lubricated within the tray.

173. To the extent this claim is deemed to require a specific structure that is not otherwise disclosed by Numata, it would have been obvious to add contouring such as a depression to the first compartment of Numata in view of Serany to accommodate the lubricant and water syringes (including their flanges) to prevent movement during shipping for the reasons at limitation 13[i].

174. This depression would perform the dual-function of serving as a shallow lubrication channel allowing the lubricant to pool in an enclosed space that is sufficient in size to lubricate an appropriate amount of the catheter (at least five inches). (Ex. 1003 ¶ 135.) The Catheterization Video discloses lubricating the catheter in the depression where the lubricant syringe is stored.



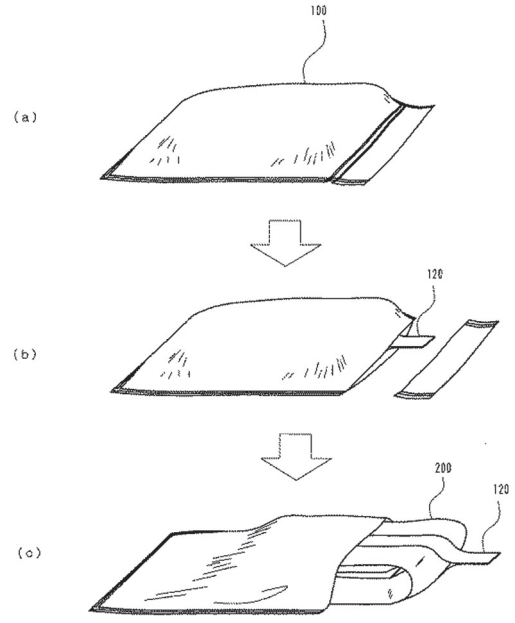
(Ex. 1020 at 2:43-49, 4:48-55.)

175. Accordingly, Numata in view of Beddow discloses this claim element.

(e) Limitation 13[e]

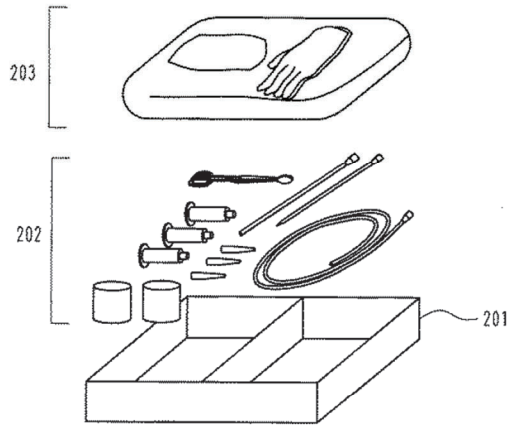
176. Numata discloses "an outer packaging disposed about the single layer tray." Numata discloses a "packaging bag 100 for sealing the medical product 200" as shown in Figure 7. (Ex. 1007 at Abstract; [0022-25], Fig. 7.)

(FIG. 7)

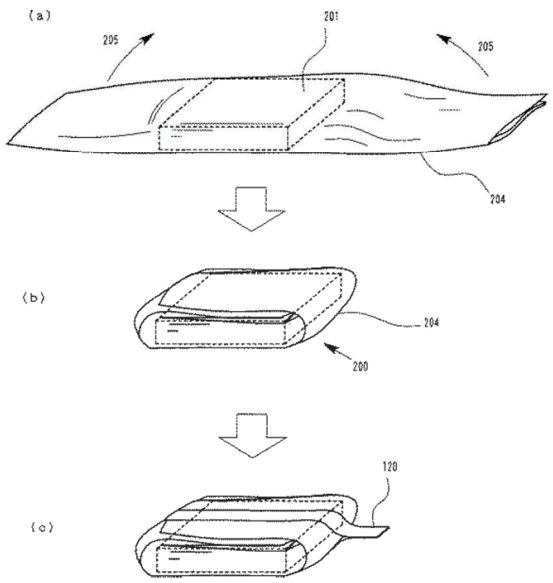


177. As shown in Figures 4 and 5 below, single layer tray 201 is wrapped in cloth 204 before being sealed by the outer packaging 100.

(FIG. 4)



(FIG. 5)



(Ex. 1007 at Abstract, ¶0031-32, Figs. 4-5.)

178. Accordingly, Numata discloses this claim element.

(f) Limitation 13[f] and [g]

179. Numata in view of Serany and Disston discloses "*one of the first syringe or the second syringe contains lubricating jelly*; *another of the first syringe or the second syringe contains water*."

180. For the reasons discussed at limitation 13[a], Numata discloses a first and second syringe. (Ex. 1009, Fig. 4, ¶ 0031.) For the reasons discussed at limitation 13[c], it would have been obvious to customize Numata's kit with a closed-system Foley catheter. Thus, while the contents of Numata's syringe are not provided, it would have been obvious to fill Numata's syringes with sterile water and lubricating jelly when using the kit of Numata for a Foley catheterization

procedure. This is a simple substitution of one element (syringes) with another (syringes filled with water and lubricating jelly) to yield predictable results.

181. A POSA would have also been motivated to fill one of Numata's syringes with lubricating jelly because a POSA would have further understood that a Foley catheter also requires lubricant to lubricate the catheter. For example, Beddow discloses "an individually sealed foil container 26 of lubricating jelly 27." (Ex. 1010 at 3:13-16.) Serany discloses "lubricating jelly in an individually sealed pouch 40." (Ex. 1009 at 3:1-5.) Disston also teaches the tray includes "lubricant," though it does not disclose a specific container for holding the lubricant. (Ex. 1008 at 4:41-45.) Indeed, the provision of lubricant in urethral catheter trays was near universal. Solazzo and Rauschenberger also provide lubricant in their urethral catheter trays. (Ex. 1005, 4:15-25; Ex. 1021 at 2:22-27.) Nursing Standard discloses a "syringe of urethral lubricant" and the Catheterization Video also show lubricant provided in a syringe. (Ex. 1019 at 52; Ex. 1020 at 2:43-2:60.)

182. A POSA would have therefore understood that lubricant can be provided in a variety of containers, and it would have been obvious to provide lubricant in a syringe as Numata already provides a kit with multiple syringes. Doing so would merely involve a simple substitution of one container (a foil container (Beddow) or pouch (Serany)) for another known type of container (a syringe as taught by Numata) to produce predictable results.

183. A POSA would further have been motivated to provide lubricant in a syringe because dispensing lubricant of the syringe may require less effort or offer more control than a packet—allowing for the efficient lubrication of the catheter. A syringe also provides a medical device connection via a Luer slip or Luer lock connection for use with caps, is less likely to leak or puncture when stacked with other rigid medical devices, and provides a controlled and measurable dispensing of lubricant. I also understand from Dr. Yun that a syringe allows for dispensing lubricant directly into the male urethra to deliver the maximum possible amount of lubricant to the patient (as compared to running the catheter through a pile of lubricant where some of it is wasted). (Ex. 1003 ¶ 49.) This method is not possible with other lubricant containers, such as a lubricant packet.

184. A POSA would have been motivated to fill another of Numata' syringes with sterile water because a POSA would have understood that a Foley catheter requires an inflation syringe to inflate the retention balloon of the Foley catheter. Serany teaches "a prefilled syringe 45 used to inflate the balloon of the catheter" that is "filled with a fixed amount of sterile water." (Ex. 1009 at 3:6-12). Disston also teaches a Foley catheter kit with an inflation syringe. (Ex. 1008 at Fig. 1; 2:44-45.) This applies a known technique (the inclusion of a sterile water syringe) to a known device ready for improvement (a catheter kit) to yield predictable results.

185. Accordingly, Numata in view of Serany and Disston discloses this claim element.

(g) Limitation 13[h]

186. Numata in view of Serany discloses "*the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure*."

187. Numata's kit includes multiple syringes in a first compartment, though it does not specify a particular order of use or arrangement of the syringes. It was well-known in the art to arrange components in a catheterization kit in their order of removal and use. For example, Serany states that "all the components [are] arranged in logical step-by-step order to facilitate the nurses or physicians task." (Ex. 1009, 1:31-35; 1:23-25.) Serany also discloses providing "components in their preferred order of use," "everything is available in the proper order of use," and "packaged in their order of use." (Ex. 1009 at 1:9-12; 1:23-35.) Further illustrating that arranging equipment in their order of use was in a Foley catheter kit was well-known, Disston discloses components that "arranged in such order and position as to be most conveniently available when the container is opened." (Ex. 1008 at 2:15-19.)

188. A POSA would have understood that items that are arranged in their order of use are also arranged in the order in which they are removed/drawn out of the tray. Indeed, Disston notes that "contents of the tray portion," including

"lubricant, syringe and water packet **are removed and put to their respective intended uses**." (Ex. 1008 at 2:41-45 (emphasis added).) Furthermore, as described in claims 4-5, Serany—which describes arranging "everything" in "the proper order of use"—discloses "**removing** the bottle 30 of cleansing solution" (stored in the left compartment) so that it can be used by "pouring it over rayon balls" (stored in the right compartment of the tray). (Ex. 1009 at Fig. 6; 2:57-72 (emphasis added).) Thus, the items of Serany are stored in their order of use (left-to-right) as well as their order of removal/order of drawing out.

189. Additionally, it was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order. "Affordances" is a term popularized by the author Donald A. Norman in his book "*The Design of Everyday Things*," which was first published in 1988. Mr. Norman notes that "affordances" as provide "strong clues as to the operation of things."

> Affordances provide strong clues as to the operation of things. Plates are for pushing. Knobs are for turning. Slots are for inserting things. Balls are for throwing or bouncing. When affordances are taken advantage of, the user knows what to do just by looking: no picture, label, or instruction is required.

(Ex. 1025 at 9.)

190. Arranging equipment in a catheter kit, such as syringe in their order of use by arranging from top-to-bottom or left-to-right is an affordance for the user of

the kit, i.e., the fact that one syringes is to the left of another provides a strong clue to the user to use the top or left syringe first.

191. For the reasons in claim 1[b] and 3, it would have been obvious to customize the contents of Numata's syringes with sterile water and lubricant. In view of Serany, it would have been obvious to organize those syringes in the first compartment consistent with their order of removal (or drawing out) and use. For example, the lubricant syringe could be positioned above or to the left of the water syringe because the lubricant step is performed before the Foley catheter is inflated with the water syringe. Alternatively, this order could be reversed if a test balloon step is performed as that requires using the water syringe first.

192. A POSA would have been motivated to arrange the syringes in their order of use in the kit of Numata. Serany provides such motivation by teaching components that are "arranged in logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:9-35.) Arranging items in their order of use makes it more likely that the user will perform operations in the correct order as well as quicker to retrieve the correct device. As explained by Serany, "[i]n using this package, the nurse or physician is assured that it will not be necessary to interrupt the procedure to search for missing items necessary to complete the job or to question the sterility of the items being used." (Ex. 1009 at 1:21-23.) Finally, this applies a known technique (arranging components left-to-right in their order of use)

to a known device (a catheter kit) ready for improvement to yield predictable results (arranging items in "a logical step-by-step order to facilitate the nurses or physicians task").

193. Finally, it would have been obvious to try arranging consistent with their order of use (e.g., left-to-right or top-to-bottom (via stacking)) because there were a finite number of identified, predictable solutions to arranging the syringes in the tray with a reasonable expectation of success.

194. Accordingly, Numata in view of Serany discloses these claim elements.

(h) Limitation 13[i]

195. Numata in view of Serany and Beddow discloses "*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*."

196. It would have been obvious to add contouring such as a depression to the lubricating jelly application compartment of Numata in view of Serany to accommodate the lubricant and water syringes (including their flanges) to prevent movement during shipping.

197. Because the tray of Numata does not provide any specific mechanism to hold the syringes in place within the first compartment of tray 201, the syringes could move during shipment of the tray. This could damage the syringes or the other

equipment disposed within the first compartment and a POSA would thus have been motivated to modify the tray of Numata to hold the syringes in place.

198. A known technique to prevent syringes from moving during shipping is to contour a tray (e.g., via a depression) to accommodate a syringe and its flange. Adding such a contour both holds the syringe in place and makes it easier to grasp the syringe. Specifically, Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a "so that it may be easily grasped," and indentations 44d to accommodate the "flange or finger grip 45c of the syringe.." (Ex. 1009 at 3:6-22 (emphasis added).) Serany notes that storing the syringe in this manner "hold[s] the syringe against lateral movement in its stored condition." (*Id. at* 3:15-16.) Depression 44 is shown in Figure 7 below:

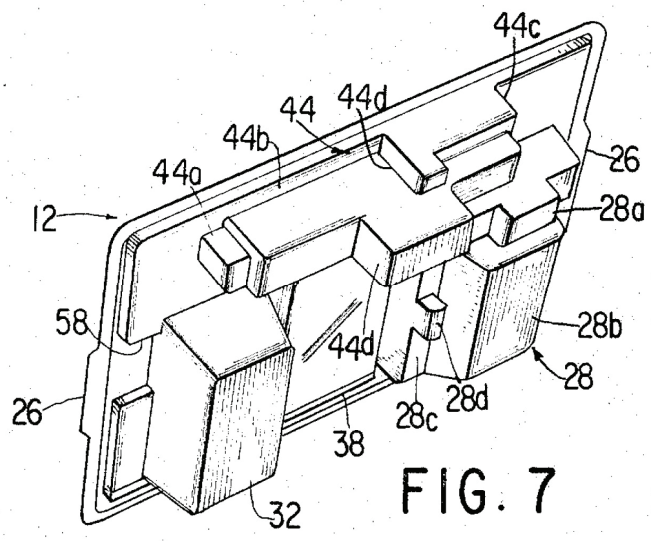
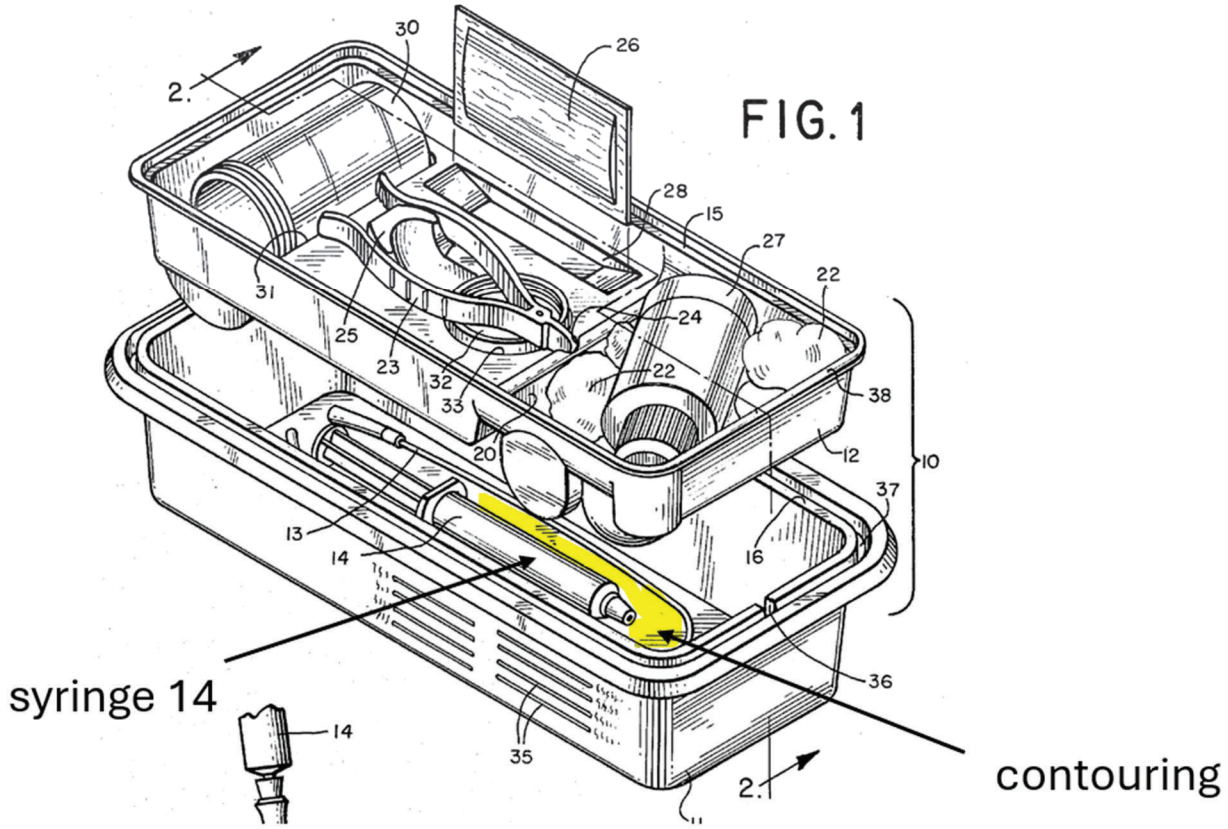


FIG. 7

199. Beddow also teaches a tray that includes contouring for holding a syringe (including its flange) as shown in annotated Figure 1 below:



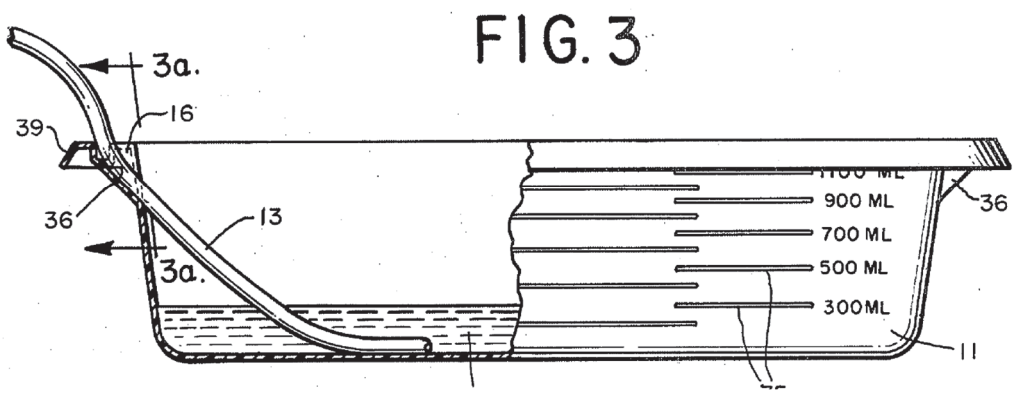
(Ex. 1010 at Fig. 1, 2:46-52, 4:14-17.)

200. It would have been obvious in view of Serany and/or Beddow to add contouring (such as a depression) to the first compartment of Numata to hold the syringe flange of one or more of the first and second syringes such that they do not move during shipping and can more easily be grasped. This applies a known technique (contouring of a compartment of a tray to hold a syringe flange) to a known device (a catheter kit with syringes) ready for improvement to yield

predictable results (preventing movement of the syringes during shipping and allow for easy grasping of the syringes.)

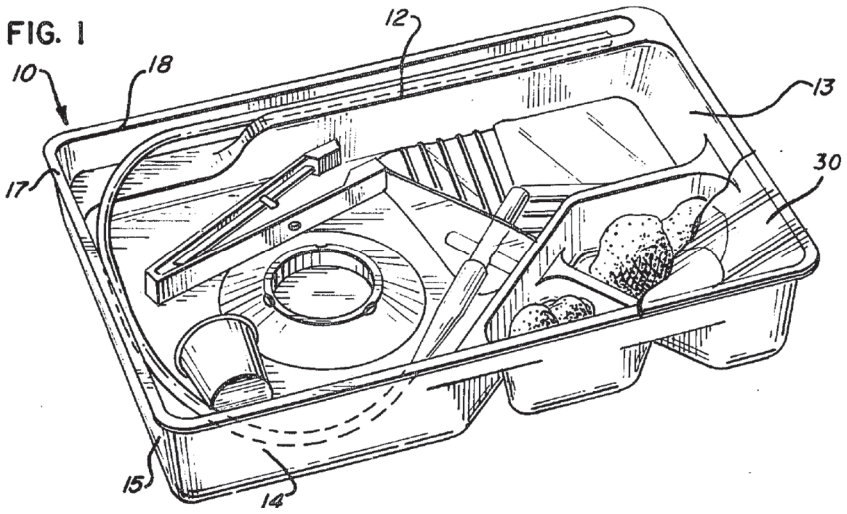
201. A POSA would understand that such contouring could easily be done when manufacturing the tray of Numata using thermoforming or injection molding techniques, either of which could be used to manufacture Numata's tray ("molded from hard plastic") tray as they were both well-known manufacturing techniques as of Numata's filing date. (Ex. 1007 ¶ 0031; *see also* (Ex. 1001 at 5:3-14 (recognizing that thermoforming and injection molding were known manufacturing methods as of the filing of the '219 Patent.) For example, Beddow discloses a thermoformed tray and Fulbrook discloses an injection molded tray. (Ex. 1010 at 2:55-57; Ex. 1029 at Figs. 1-5, Abstract; 3:61-62; 5:50-53; 11:61-64.)

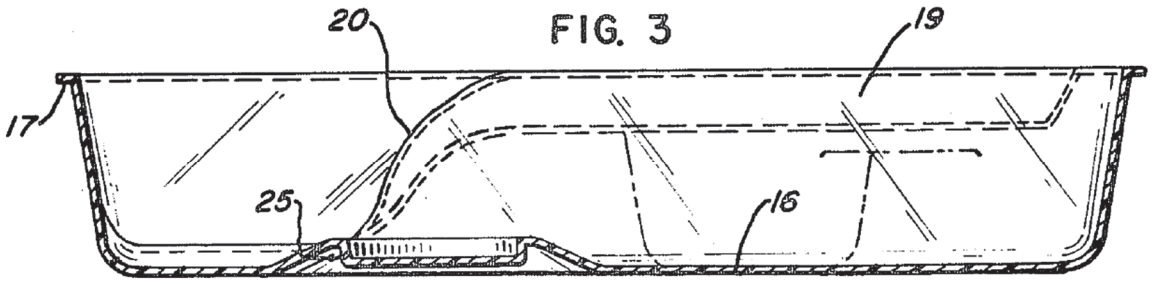
202. A POSA would have further understood that adding such contouring can be done while maintaining a flat base member to maintain stability of the tray. For example, the bottom tray of Beddow has a flat base member as shown in Figure 3 (above), but includes contouring to hold a syringe (as shown in Figure 1 above) within a raised compartment of the tray:



203. Although Numata's compartment is not deep as discussed above, providing syringes in a raised compartment as shown by Beddow also has the advantage of making the syringes (as well as the lubrication compartment) easier to access. The syringes could be arranged in this compartment in a left-to-right configuration for the reasons at limitations 4 and 5 below.

204. Likewise, Rauschenberger discloses a flat base member with various contouring to hold components, such as recess 26 that is contoured to hold a specimen cup, illustrating that such contouring is also possible with injection molding techniques. (Ex. 1021 at 2:55-60; Figs. 1-3.)





205. As evidenced by Serany's 1965 filing date, Rauschenberger's 1977 filing date, and Beddow's 1979 filing date the manufacturing techniques used to add such contouring to a tray to hold components were very well-known by 2009.

206. Numata in view of Serany, Disston, and Beddow therefore disclose this claim element. Numata in view of Serany, Disston, and Beddow therefore renders claim 13 obvious.

2. Independent Claim 1

(a) Limitation 1[p]

207. For the reasons at limitation 13[a], Numata discloses "*A medical procedure kit*."

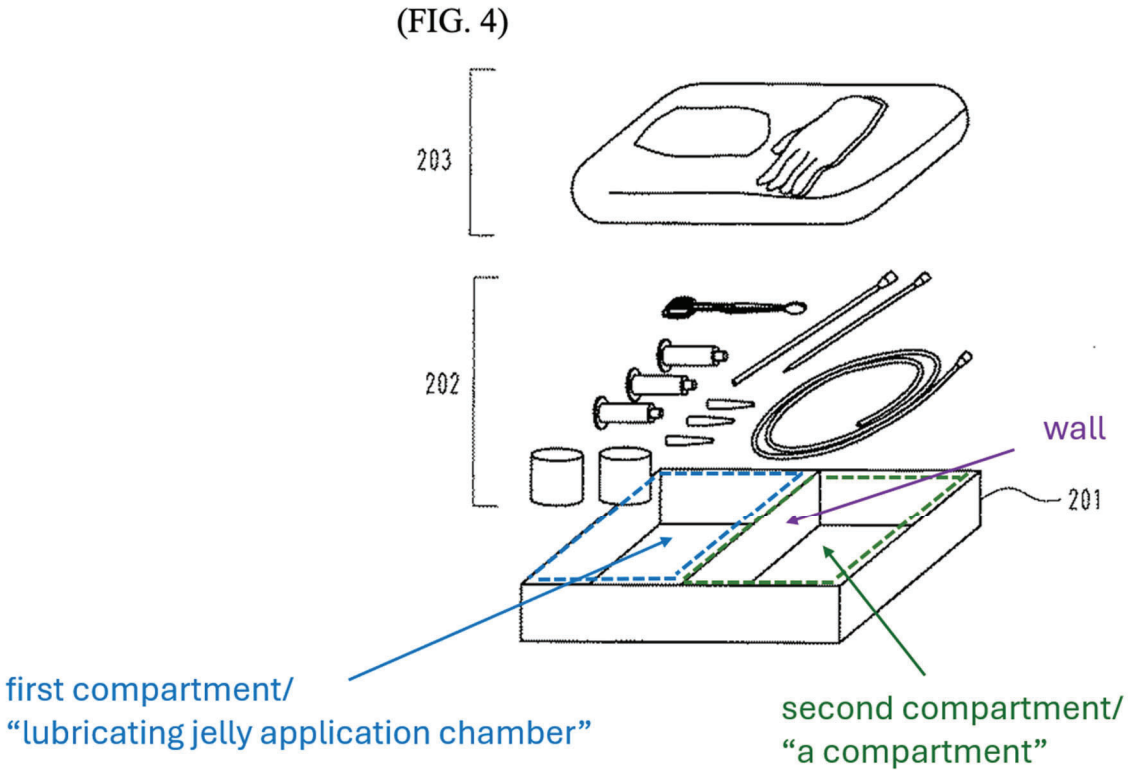
(b) Limitation 1[a] and 1[d]

208. For the reasons at limitations 13[a] and [d], Numata in view of Beddow and Serany discloses *"a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber*" and "*the lubricating jelly application chamber is configured to receive lubricating jelly*" obvious.

209. As discussed above, independent claim 13 requires a first compartment that is "a lubricating jelly application chamber" and a "second compartment" that stores a closed-system Foley catheter. Independent claim 1 requires "**a compartment** separated by a wall from **a lubricating jelly application chamber**." Accordingly, for both claims 1 and 13, the left compartment of Numata the claimed "first compartment" or "lubricating jelly application chamber." For both claims 1 and 13, the right compartment is the claimed "second compartment" or "a compartment."

210. Specifically, as shown in annotated Figure 4 below, the "lubricating jelly application chamber" of claim 1 and the "first compartment of claim 13" are both the left compartment of Numata. The "a compartment" of claim 1 and the "second compartment" of claim 13 are both the right compartment of Numata.

These compartments are separated by a wall thus meeting that requirement of limitation 1[a].



(c) Limitation 1[b], [e], [f]

211. For the reasons at limitation 13[f], Numata in view of Beddow and Serany discloses "*a container of lubricating jelly disposed within the single layer tray*," "*the container of lubricating jelly comprising a syringe containing the lubricating jelly*," and *the syringe situated within the lubricating jelly application chamber*" obvious.

(d) Limitation 1[c]

212. For the reasons at limitation 13[b], Numata in view of Serany and Disston discloses "*a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit*" obvious.

213. Numata in view of Serany, Disston, and Beddow therefore renders claim 1 obvious.

3. Claims 3 and 10

214. For the reasons at limitation 13[g], Numata in view of Serany and Disston discloses "*a syringe containing water disposed within the single layer tray*," (claim 3) and "*the second syringe contains water*" (claim 10).

215. Numata in view of Serany, Disston, and Beddow therefore renders claims 3 and 10 obvious.

4. Claims 9 and 14

216. For the reasons at limitation 13[g], Numata in view of Serany and Disston discloses "*the second syringe is for attachment to the Foley Catheter*," (claim 9), and "*the second syringe is attachable to the Foley catheter*" (claim 14). As discussed at claim 13[g], it would have been obvious to include an inflation syringe in the kit of Numata to inflate the retention balloon of a Foley catheter. A POSA would further have understood that an inflation syringe must be attached to the inflation port of a Foley catheter to inflate the balloon. An inflation syringe only

functions by being attached to the inflation port of a Foley catheter as water must be injected into the catheter to inflate the balloon. Thus, "the second syringe" (i.e., the sterile water syringe) "is for attachment to the Foley catheter."

217. Indeed, it was well-known that inflation syringes are attached to Foley catheters for inflation of the balloon. Disston describes using the water syringe to inflate the catheter balloon and shows the water syringe attached to the Foley catheter inflation portion (valve 12) in Figure 1:

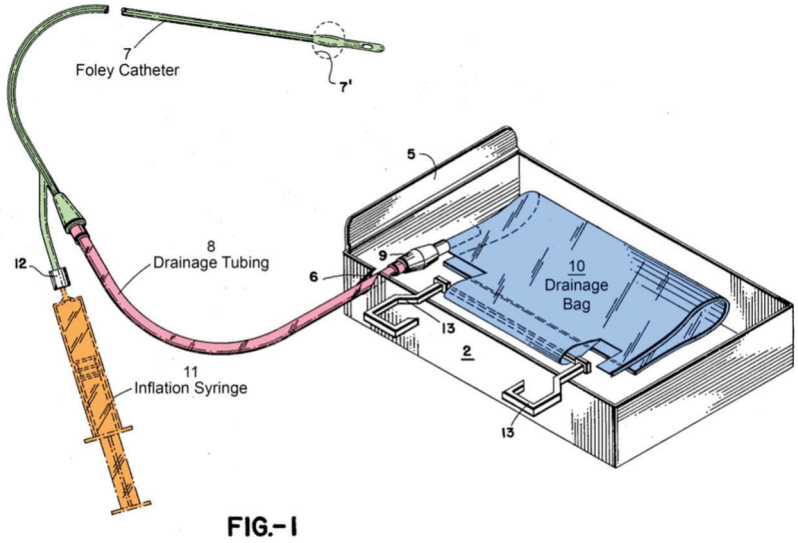


FIG.-1

(Ex. 1008 at Fig. 1; 1:41-53.) Serany also discloses "The covering 47 on the tip of the syringe 45 is removed and the balloon on the catheter is inflated with the sterile water in the syringe 45." (Ex. 1009 at 3:6-12, 3:49-52.)

218. Accordingly, Numata in view of Serany and Disston discloses this claim element. Numata in view of Serany, Disston, and Beddow therefore renders claims 9 and 14 obvious.

5. Claims 4, 5, and 11

219. For the reasons at 13[h], Numata in view of Serany and Disston discloses "*wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in a left-to-right configuration*" (claim 4), "*wherein the left-to-right configuration comprises a left-to-right usage configuration*" (claim 5), and *wherein the syringe and the second syringe are arranged in the single layer tray in accordance with an order of use during a Foley catheterization procedure*" (claim 11).

220. As discussed at 13[h], it would have been obvious to arrange the syringes of Numata in accordance with their order of use during a Foley catheterization procedure. One known way of arranging items in their order of use was to arrange them from left-to-right consistent with their order of use.

221. Serany specifically discloses items arranged from left-to-right in their order of use. As shown in annotated Figure 6 below, the bottle of cleansing solution 30 is stored in compartment 28 to the left of the rayon balls 34, which are stored in compartment 32. (Ex. 1009 at Fig. 6; 2:57-72.) In operation, Serany discloses "removing the bottle of cleansing solution from compartment 28, as previously

described, and pouring it over the rayon balls 34 in their stored position in the depression 32." (*Id.*) The rayon balls are used removed from the kit with the forceps and used later in the procedure. (*Id.*) Thus, Serany discloses removing and using an item stored to the left of another item in the kit—consistent with Serany's description of all items being stored "in their order of use." (Ex. 1009 at 1:9-12; 1:23-35.)

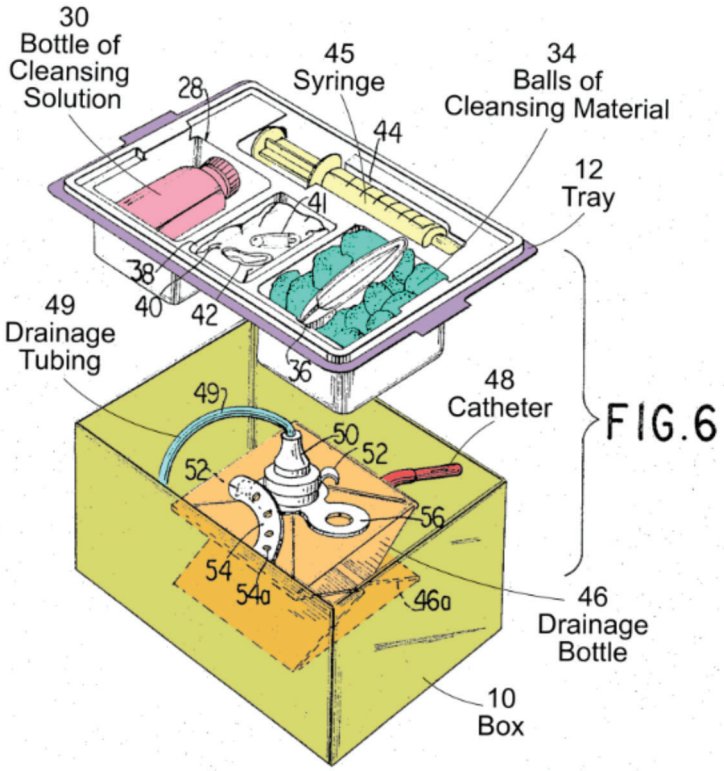


FIG.6

222. As illustrated by Serany, storing items in a left-to-right position consistent with their order of use was well-known in the art. Indeed, Vagley discloses a surgical tray where the medical instructions are positioned "in a sequence

going from **left to right**," which is the order in which the instruments are "employed for a particular surgical procedure" (i.e., used during the procedure.) (Ex. 1027 at 3:15-25 (emphasis added); 4:26-28; Fig. 1.)

223. Thus, in view of Serany, it would have been obvious to arrange the syringes in a left-to-right usage configuration consistent with their order of use. This applies a known technique (arranging equipment of a catheter kit in their order of use) to a known device (a catheter kit) to yield predictable results (providing an affordance for the user of the kit by organizing the equipment in a "logical step-by-step order" as taught by Serany.) (Ex. 1009, 1:31-35; 1:23-25.)

224. Further, it would have been obvious to try arranging the syringes left-to-right consistent with their order of use because there were a finite number of identified, predictable solutions to arranging the syringes in their order of use (i.e., placing the syringes left-to-right and/or at different heights) with a reasonable expectation of success.

225. Accordingly, Numata in view of Serany and Disston discloses these claim elements. Numata in view of Serany, Disston, and Beddow therefore renders claims 4, 5, and 11 obvious.

6. Claims 6 and 7

226. For the reasons at 13[h] and claims 4 and 5, Numata in view of Serany and Disston discloses "*wherein the syringe containing the lubricating jelly and* [*the*

syringe containing the water (claim 6) */second syringe* (claim 7)] *are arranged within the single layer tray in accordance with an order with which the syringe containing the lubricating jelly and the* [*syringe containing the water/second syringe*] *are* [*removed* (claim 6) */drawn out* (claim 7)] *from the single layer tray*" obvious.

227. Accordingly, Numata in view of Serany and Disston discloses these claim elements. Numata in view of Serany, Disston, and Beddow therefore renders claims 6 and 7 obvious.

7. Claim 12

228. For the reasons at limitation 13[i], Numata in view of Serany and Beddow discloses "*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*."

229. Numata in view of Serany, Disston, and Beddow therefore renders claim 12 obvious.

C. Ground 2: Obviousness Over Numata, Serany, Disston, and Beddow and Salvadori (Claim 2)

1. Claim 2

230. Claim 2 requires "*the medical kit comprising one or more swabsticks disposed within the single layer tray*." Numata in view of Salvadori discloses "*the medical kit comprising one or more swabsticks disposed within the single layer tray*." When customizing the kit of Numata to include urinary catheter equipment for the reasons at limitation 13[b], it would have been obvious to add swabsticks to the

single layer tray of Numata because it was well-known to provide equipment for cleaning the patient's genitals prior to catheter insertion in urinary catheter kits.

231. Specifically, it was well-known to include equipment for cleaning the patient such as an absorbent material along with means to grasp the absorbent material. (Ex. 1009, 1:12-16; 3:4 (disclosing forceps and rayon ballons); Ex. 1021, 2:43-57 (disclosing forceps and absorbent pads); Ex. 1010, 2:66-3:10 (disclosing forceps and balls); (Ex. 1009, 1:12-16; 3:4; Fig. 1 (disclosing swabsticks).) The absorbent material (a ball, swab, or pad) is used to clean the patient's genitals, typically after cleansing solutions are poured on the absorbent material. For example, Serany states: "Conventionally, the balls of cleansing material are unsaturated with a cleansing solution before they are used. This is readily accomplished in the present invention, by removing the bottle 30 of cleansing solution from the compartment 28, as previously described, and pouring it over the rayon balls 34 in their stored position in the depression 32." (Ex. 1009 at 2:60-65; 3:45-48; *see also* Ex. 1010 at 2:60-3:20 (noting that balls and forceps are "used in preparing the patient for catheterization.") Rauschenberger also notes that "the patient is cleansed with the saturated absorbent pads by holding the forceps.) (Ex. 1010 at 2:50-51.) In the case of swabsticks, the cleansing material is often pre-applied, i.e., pre-saturated.

232. As discussed above, the two common forms of such equipment were (1) forceps and balls or pads and (2) swabsticks. A swabstick merely provides a handle

attached to an absorbent material (a swab) as opposed to using forceps to pick up the absorbent material. Although Numata does not expressly disclose a urinary catheter kit, it includes similar equipment (forceps and degreasing cotton) within its single layer tray (specifically, in the left compartment of tray 201 as shown in Figure 4, which also has ample room to accommodate the swabsticks). (Ex. 1007 ¶ 31; Fig. 4.)

233. Salvadori teaches a "urethral catheter kit or tray" that includes "swab sticks 60." (Ex. 1013, 1:12-16; 3:4; Fig. 1.) In view of Salvadori, a POSA would have been motivated to include swabsticks in the catheterization kit of Numata to allow a practitioner to cleanse the patient's genitals prior to insertion of the catheter.

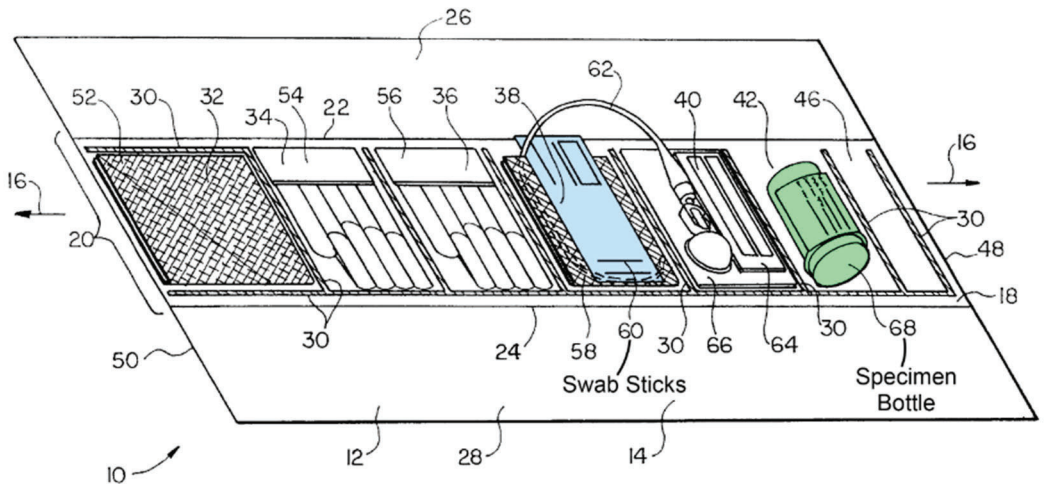


FIG. 1

234. The inclusion of swabsticks in the catheterization kit of Numata involves the use of a known technique (provision of swab sticks) to a known device (a Foley catheter kit) ready for improvement to yield predictable results. This is also

a simple substitution of one known element (forceps and cotton) as taught by a Numata with another (swabsticks (i.e., a cotton swab with a handle)) to yield predictable results.

235. Additionally, it would have been obvious to try including swabsticks given the finite number of available options for equipment used to clean the patient (i.e., an absorbent material with a handle (a swabstick) or absorbent material that must be picked up with forceps.

236. A POSA would have further been motivated to include swabsticks over the other available options because a swabstick is easier to manipulate than forceps. Specifically, a clinician could inadvertently drop a ball or pad if they do not maintain constant pressure with the forceps to grasp the ball/pad, but this is less likely to occur with a swabstick, which can simply be picked up by its handle.

237. Accordingly, the combination of Numata in view of Salvadori discloses this claim element. Numata in view of Serany, Disston, Beddow and Salvadori therefore render claim 2 obvious.

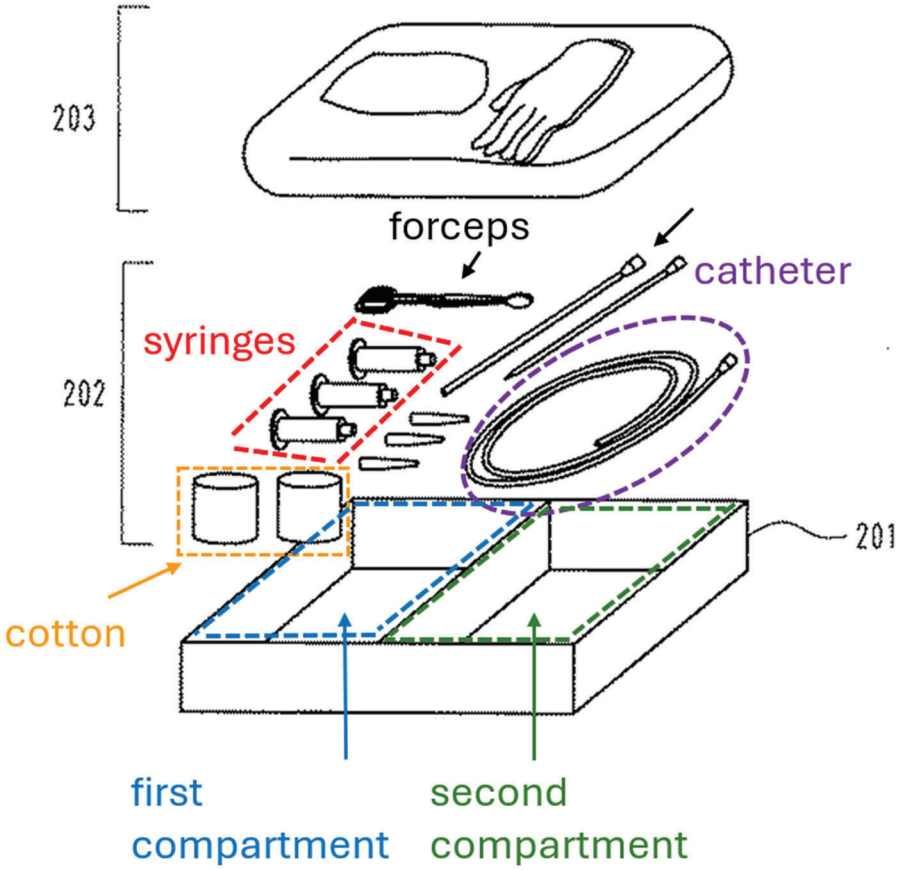
D. Ground 3: Obviousness Over Numata, Serany, Disston, Beddow, Imai and Salvadori (claims 15-16)

1. Claim 15

238. Numata in view of Salvadori and Imai discloses "*wherein the single layer tray comprises a third compartment containing one or more swabsticks*." For the reasons at claim 2, it would have been obvious to add swabsticks to the kit of

Numata by substituting Numata's forceps and cotton for swabsticks. Numata's "forceps" and "cotton" are stored in the left compartment as shown in annotated Figure 4 below, which also houses the syringes:

(FIG. 4)

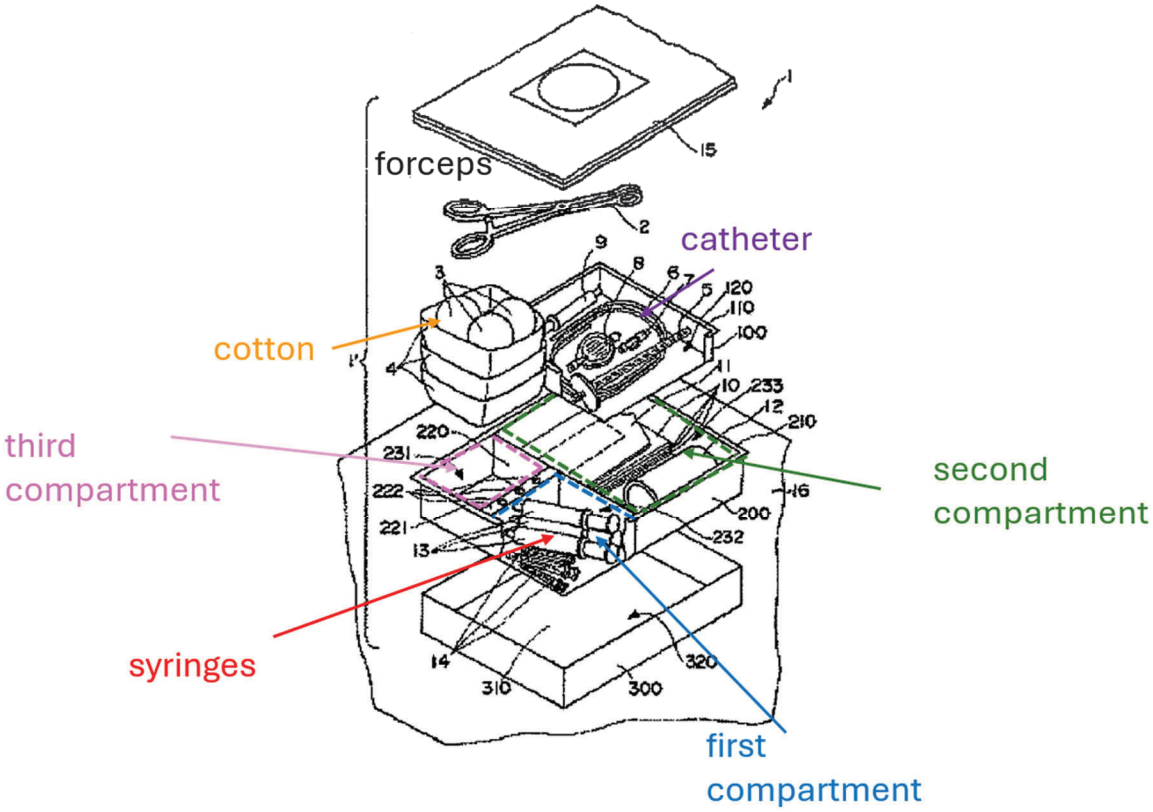


(Ex. 1007 at Fig. 4, ¶ 0031.)

239. Catheter kits with three compartments were well-known in the art. For example, Imai, Serany, Rauschenberger, and Beddow all disclose trays with at least three compartments for organizing the equipment stored in the kit. (Ex. 1009 at Figs. 6-7, Ex.1010 at Fig. 1; Ex. 1023 at Fig. 2; Ex. 1021 at Figs. 1-2.)

240. For example, as with Numata, Imai discloses a catheter kit with a catheter 6, syringes 13, forceps 2, and cotton balls 3 stored in a tray. Whereas Numata stores the cotton and syringes in the same left compartment, Imai divides the left portion of tray 200 into two compartment. Specifically, within tray 200, Imai includes "three storage cells 231 to 233" (i.e., three compartments) to store its catheter equipment as shown in annotated Figure 1 below:

[Figure 1]



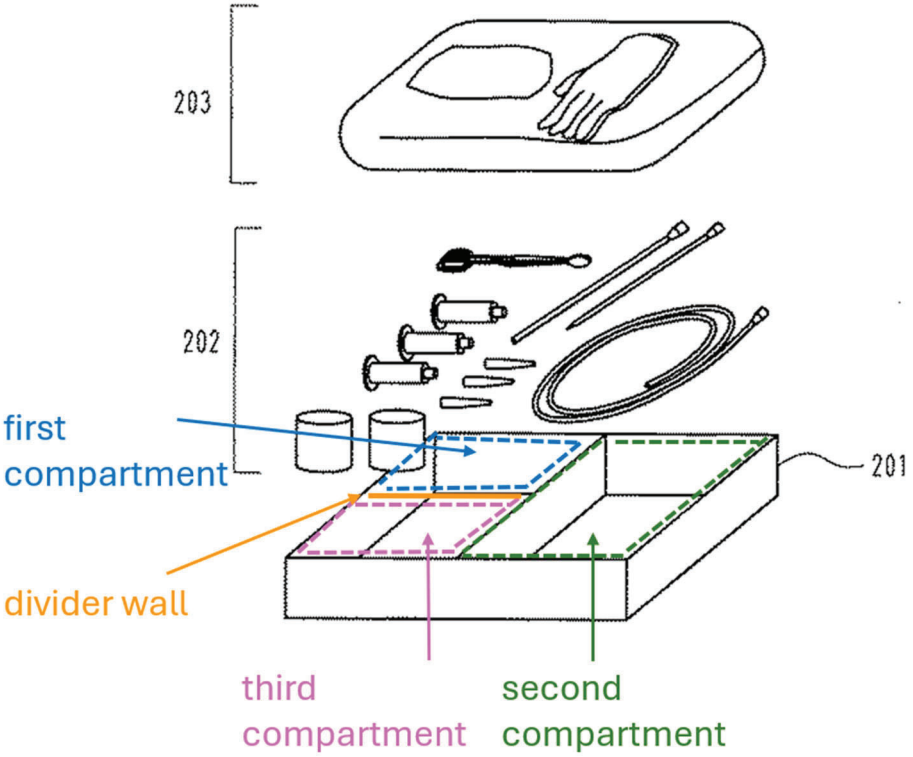
(Ex. 1012 at Abstract; Fig. 1).

241. Specifically, the syringes are stored in a first compartment (storage cell 232), a catheter is stored in a second compartment (233), and cotton is stored in a

third compartment (storage cell 231). (Ex. 1012 at Fig. 1; ¶¶ 0014, 0018-0021; 0028; 0045.) "Tray 200 is "partitioned" into "three respective cells" (i.e., compartments) via "partitioning member 220" (i.e., a divider wall). (*Id.* ¶ 0019.) Imai notes that "partitioning member 220" "fortifie[s]" the strength of tray 200 and "functions as a movement-restricting means to prevent the treatment tools housed within second small tray 200 and first small tray l00 from freely moving around." (*Id.* ¶ 0020.)

242. In view of Imai, a POSA would have been motivated to add an additional partitioning member to tray 201 of Numata to fortify the strength of the tray and "to prevent the treatment tools housed within … from freely moving around." (*Id.*) Specifically, a POSA would have recognized that the cotton and forceps (replaceable with swabsticks) could freely move around the left compartment of Numata during shipping within a compartment that houses other items, including syringes. Thus, to prevent such items from freely moving around during shipment of the tray, it would have been obvious to add an additional compartment by adding an additional divider wall to the left compartment of Numata to divide it into a first and third compartment as shown in annotated Figure 1 below:

(FIG. 4)



243. Numata already discloses one divider wall to separate the two compartments in tray 201 so adding a third compartment would via an additional divider wall would be well within the knowledge and skill of a POSA in view of known manufacturing techniques. Indeed, Imai's "partitioning member 220" divides the tray into three compartments in the same manner proposed here (i.e., a large compartment on the right and two smaller compartments on the left.) Moreover, adding an additional divider wall to Numata would separate the same equipment (syringes and cotton) that partitioning member 220 separates in Imai. This applies a known technique (adding a third compartment via an additional divider wall) to a known device (a catheter kit) to yield predictable results

(preventing equipment from moving around in the tray). It also would have been obvious to try given the finite number of ways to store equipment in a catheter kit (together in a single compartment or in separate compartments).

244. There would also have been a reasonable expectation of success in combining Numata and Imai. Both patents are directed to catheter kits with similar equipment (a coiled catheter, syringes, cotton, forceps) stored in a tray that is covered in a wrap and outer bag. (Ex. 1009 at Abstract; Figs. 4-6; Ex. 1012 at Fig 1; ¶ 0014; 0064-0072.) The tray of Numata is "molded" from a "hard plastic or the like" and tray 200 of Imai can also be made from various plastics. (Ex. 1009 ¶ 0014; Ex. 1012 ¶ 0017.)

2. Claim 16

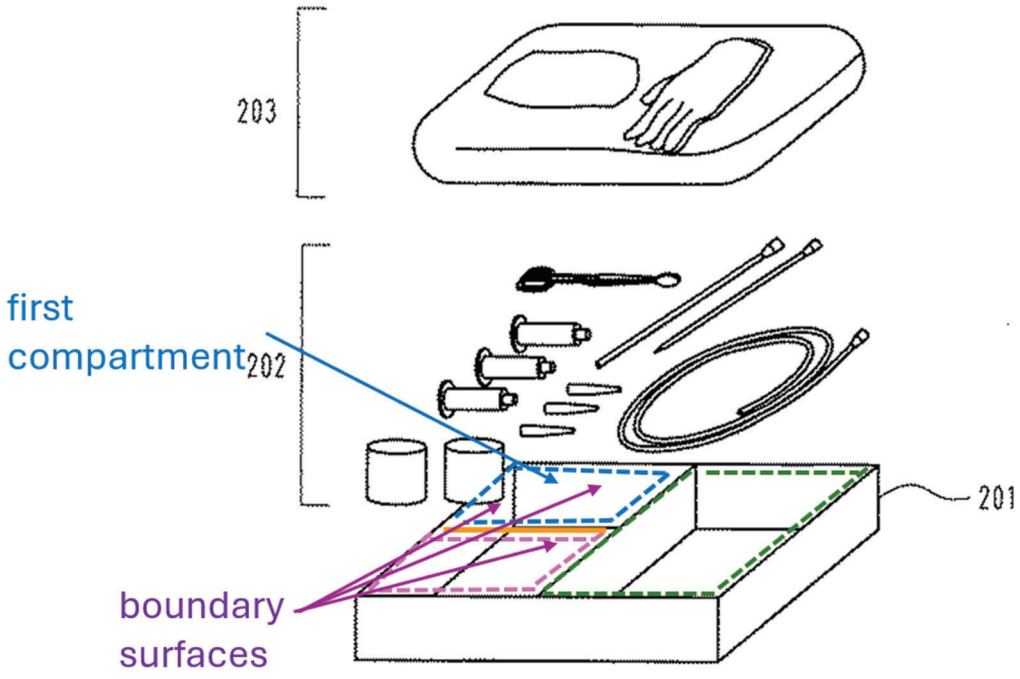
245. Claim 16 requires "*wherein a boundary surface defines the lubricating jelly application chambe*r."

246. For the reasons in claim 13[d] above, Numata in view of Beddow discloses a "*lubricating jelly application chamber*" in the left (or first) compartment of Numata. Numata further discloses "*wherein a boundary surface defines the lubricating jelly application chamber*."

247. I note that that term "boundary" does not appear in the '219 patent outside of claim 16. I have thus applied the plain meaning of "boundary surface," which I understand to be a surface that delineates the boundaries of the tray. The

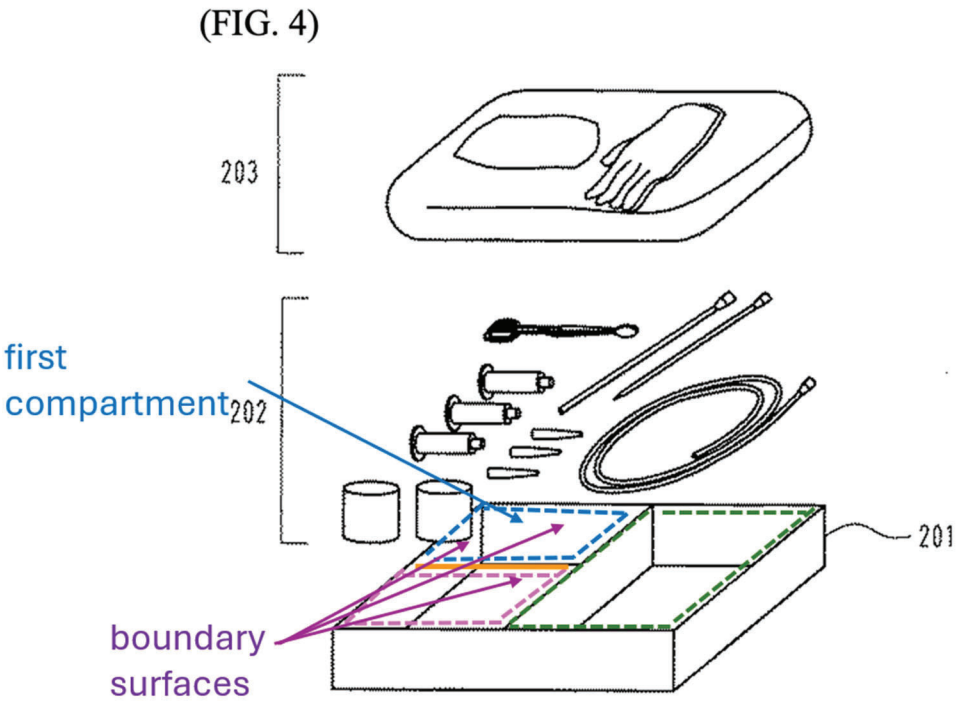
boundary surfaces of the first compartment of Numata (i.e., the "lubricating jelly application chamber") are thus the bottom surface of the tray and the outer walls. (Ex. 1007 at Fig. 4.)

(FIG. 4)



248. Such surfaces define the first compartment because the first compartment is bounded on the bottom by the bottom surface of the tray and on the sides by portions of the outer wall of the tray. Additionally, as described above, the first compartment is a lubricating jelly application chamber because the lubricant would be dispensed on the bottom surface of the tray—meaning, "*a boundary surface defines the lubricating jelly application chambe*r." As discussed at claim 15,

it would have been obvious to divide Numata into three compartments as shown in annotated Figure 4 below:



249. In this configuration, Numata still discloses that "*wherein a boundary surface defines the lubricating jelly application chamber*," because the bottom surface of the first compartment and portions of the outer wall define the first compartment, and thus "*the lubricating jelly application chamber*."

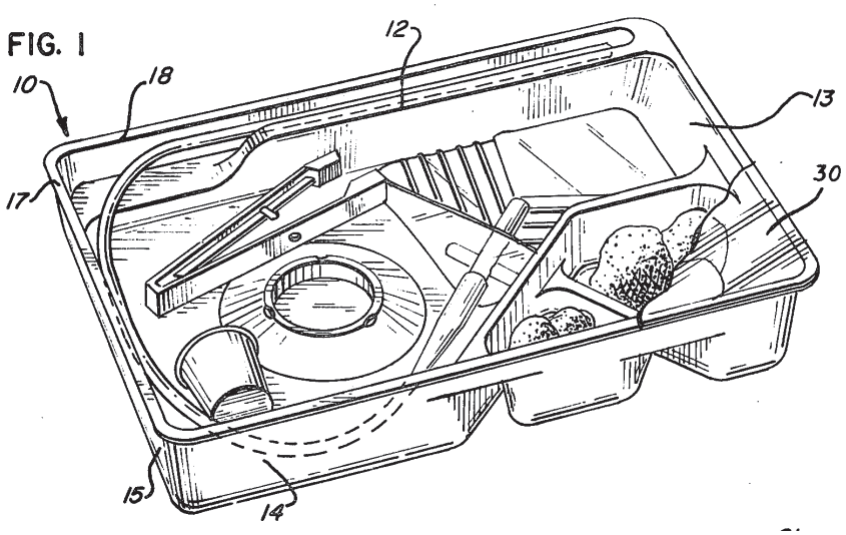
E. Ground 4: Obviousness Over Rauschenberger and Serany (claims 13-14)

1. Independent Claim 13

(a) Limitations 13[p] and 13[a]

250. Rauschenberger in view of Serany discloses "*A medical procedure kit, comprising: a first syringe and a second syringe*."

251. Rauschenberger discloses a "urethral catheterization tray" 10 (as shown below in Fig. 1), which is a medical procedure kit as it includes a urethral (or urinary) catheter and equipment to perform a urinary catheterization. (Ex. 1021 at Abstract, 1:61-2:68, Fig. 1.)

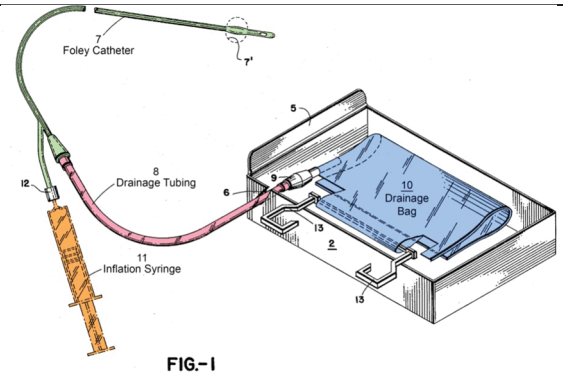
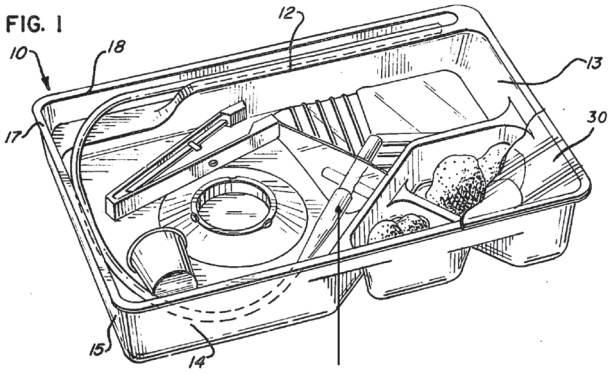


252. **First Syringe – Lubricant Syringe.** There are two types of urethral (or urinary) catheters: an intermittent catheter, used to relieve the bladder of one-time, and an indwelling Foley catheter, which includes a retention balloon such that the catheter can remain inserted for several days. (Ex. 1003 ¶¶ 27-30.) All-in-one urethral catheter kits (like Rauschenberger) include lubricant (which may be provided in a variety of containers, including a syringe) to lubricate the catheter before insertion.

253. Specifically, Rauschenberger discloses one of the components of the tray is a "lubricant packet" to lubricate the catheter. (Ex. 1021 at 2:22-3:33.) It

would have been obvious to substitute Rauschenberger's lubricant packet with a lubricant syringe. Doing so would merely involve a simple substitution of one container (a lubricant packet as taught by Rauschenberger) for another known type of container (a syringe) to produce predictable results. A lubricant syringe provides more control than a lubricant packet and allows for the injection of lubrication directly into the male urethra. (Ex. 1003 ¶ 49.)

254. **Second Syringe – Water Syringe.** Foley catheter kits include both lubricant and an inflation syringe (supplied with sterile water) to inflate the retention balloon. For example, Serany, Disston, and Solazzo each include an inflation syringe. (Ex. 1009 at 3:6-12, 3:49-51; 1008 at Fig. 1; 2:44-45; Ex. 1005, 3:15-24.) The urethral catheter of Rauschenberger is generically referred to as a "catheter" throughout the specification and claims. (Ex. 1021 at 1:62:2-46, claims 1-2.) But Rauschenberger does not expressly mention that the kit is provided with an inflation syringe. And the catheter of Rauschenberger is not depicted as including an inflation port (as shown by a comparison with Solazzo, which expressly discloses a Foley catheter):

Solazzo	Rauschenberger
 FIG.-1	 no inflation port

255. Thus, a POSA would understand the "urethral catheter" of the preferred embodiment of Figure 1 of Rauschenberger to likely be an intermittent catheter. However, the invention of Rauschenberger is in no way limited to intermittent catheters. Rauschenberger generally discloses "a urethral catheterization tray" with a "catheter" and "drainage bag." And Rauschenberger notes that "[c]hannel 21 is adapted to receive a conventional urethral catheter." (Ex. 1021 at 1:62-63.) A POSA would understand both a Foley and intermittent catheter to be conventional urethral catheters as of Rauschenberger's 1977 filing date.[2] Further, as Dr. Yun explains, intermittent and Foley catheters are similarly sized as they are both designed to fit within the urethra. (Ex. 1003 ¶¶39.) Thus, a compartment "adapted to receive a

[2] Foley catheters were invented in the 1930s. Serany and Disston were patented in the 1960s and are directed to Foley catheter kits. Intermittent catheters were also well-known at the time. Beddow (1979) discloses an intermittent catheter.

conventional urethral catheter" would be understood by a POSA to be able to receive either an intermittent or Foley catheter.

256. It would have been obvious to a POSA to provide a Foley catheter in the tray of Rauschenberger. I understand from Dr. Yun that the decision whether to insert an intermittent or Foley catheter is a clinical determination based on the patients' needs, i.e., a one-time draining of the bladder or repeated draining over a longer duration. (Ex. 1003 ¶ 30.) There would have been motivation to equip Rauschenberger with a Foley catheter to allow the invention of Rauschenberger to be used with the other common type of urethral catheterization (i.e., Foley catheterization).

257. When equipping Rauschenberger with a Foley catheter, it would have been obvious to add an inflation syringe to the kit of Rauschenberger so that its retention balloon can be inflated. Rauschenberger discloses common equipment needed to perform an intermittent catheterization procedure (e.g., lubricant, gloves, antiseptic solution). Thus, there would have been a motivation to include an inflation syringe (such as the inflation syringe provided by Serany) with the kit of Rauschenberger to allow for a complete Foley catheterization procedure to be completed, which requires an inflation syringe. This also applies a known technique (provision of an inflation syringe) to a known device (a urethral catheter kit) to yield predictable results (allowing the procedure to be completed.)

258. Serany provides motivation by describing an all-in-one Foley catheter kit that includes an inflation syringe, and notes "all the essential equipment, including preparation items, catheter, and drainage bottle, for a complete [] catheterization procedure are included in the package. In using this package, the nurse or physician is assured that it will not be necessary to interrupt the procedure to search for missing items necessary to complete the job." (Ex. 1009 at 1:16-22; 3:5-7; 3:49-51.)

259. There would have been a reasonable expectation of success in combining Rauschenberger with because both references are directed to all-in-one urethral catheter kits. All the equipment disclosed by Rauschenberger ("gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container") is also equipment used with Foley catheters. (Ex. 1021 at 2:24-26; Ex. 1009 at 2:21-32; 2:61-73; 3:1-5; 3:23-34.) Thus, this combination merely requires substituting Rauschenberger's closed-system intermittent catheter with Serany's closed-system Foley catheter (as discussed at limitation 13[b] below) and to add an inflation syringe.

260. Moreover, the purported benefit of the claimed invention of Rauschenberger applies equally to intermittent and Foley catheters. Rauschenberger states that with "prior art devices," the clinician would "place[] an amount of lubricant on the CSR wrap" to lubricate the catheter and on the wrap to clean the

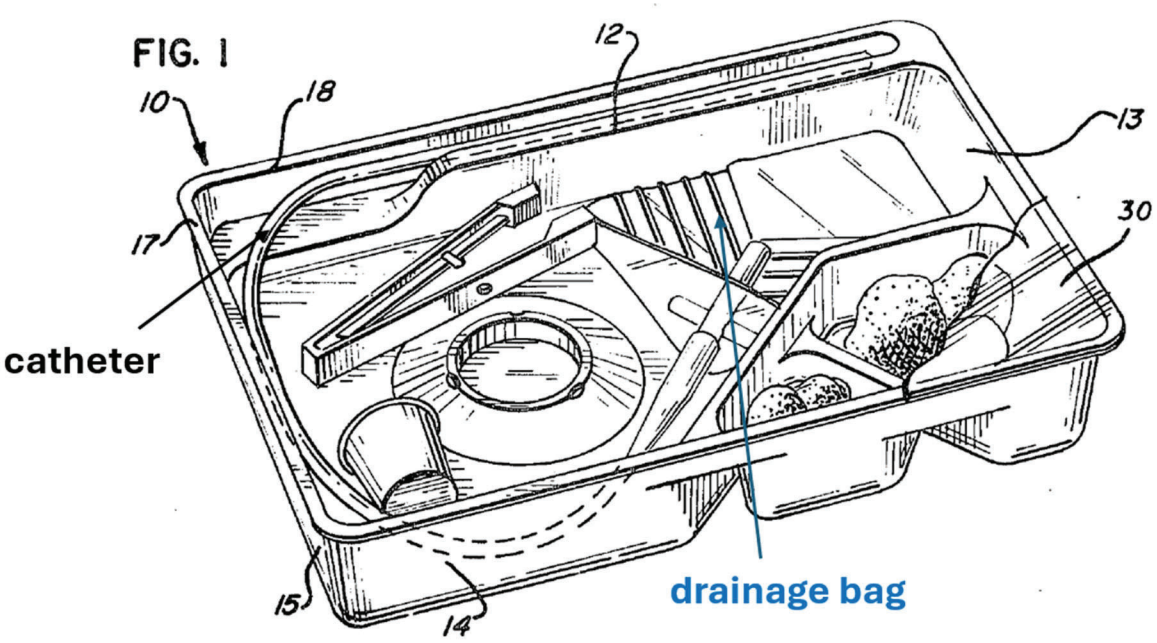
patient. (Ex. 1021, 1:7-43.) This was "less than ideal" because the lubricant could "contact" the patient or clinician. (*Id.*) Thus, Rauschenberger provides a tray where catheterization procedure steps, such as lubricating the catheter, can be performed within the tray itself. (Ex. 1021, 1:44-2:43.) This applies equally to Foley catheter kits as both intermittent and Foley catheters must be lubricated before inserting the catheter.

261. Accordingly, Rauschenberger in view of Serany discloses this claim element.

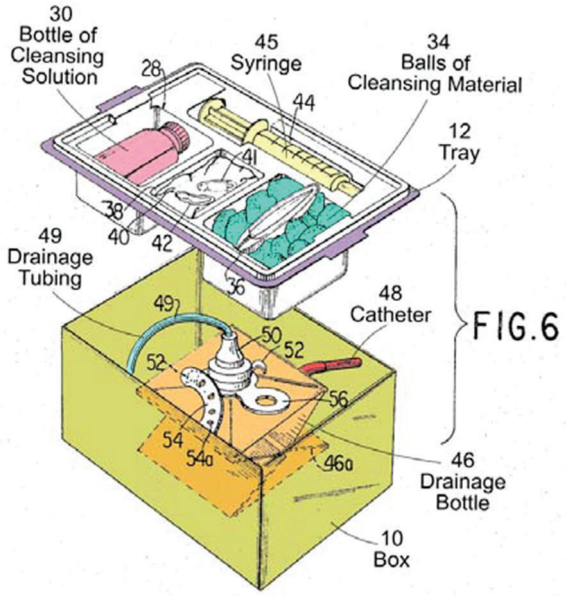
(b) Limitation 13[b]

262. Rauschenberger in view of Serany discloses "*the medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*."

263. As discussed at claim 13[a], Rauschenberger discloses a "urethral catheter" and a "drainage bag." (Ex. 1021 at Abstract, 2:20-25.) The urethral catheter is attached to the drainage bag as shown in Figure 1:



264. Serany is directed to an all-in-one Foley catheter kit and discloses "*a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*." Specifically, Serany discloses "a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use." (Ex. 1009 at 3:23-26.") The drainage tubing that couples the fluid drainage bag and Foley catheter is coiled: "The catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex. 1009 at 3:32-34.)



265. For the reasons at claim 13[a], it would have been obvious to substitute Rauschenberger's urethral catheter (an intermittent catheter attached to a drainage bag) with Serany's urethral catheter (a Foley catheter attached to a drainage bag via coiled tubing). This is a simple substitution of one type of well-known urethral catheter (a closed-system intermittent catheter) for another (a closed-system Foley catheter). Specifically, the catheter/bag of Rauschenberger could be replaced with the catheter/bag/coiled tubing of Serany.

266. The reason that Serany attaches its Foley catheter via coiled tubing is that drainage bags are typically hung from the side of a bed requiring a long run of tubing, which then must be coiled to fit within the confines of typical packaging. (Ex. 1009 at 3:36-44 (describing Serany's drainage bottle being attached to a bed rail).) Thus, when adding a Foley catheter to the kit of Rauschenberger, it would be

supplied with a longer run of tubing, which would need to be coiled to fit with the main compartment of Rauschenberger. As taught by Serany, the tubing can be coiled around the bottle/bag such that it would also fit within the tray of Rauschenberger.

267. Although Serany refers to the catheter as being connected to a "drainage bottle," it describes the "bottle" as being made out of a "flexible plastic material" that can be collapsed inside the box. (Ex. 1009 at 3:26-32; Fig. 6.) A POSA would understand Serany to therefore teach a fluid bag because a collapsible drainage receptacle made of a flexible plastic material could also be considered a bag. To the extent Patent Owner argues that Serany does not teach a bag, it would have further been obvious to substitute the "drainage bottle" of Serany with Rauschenberger's "drainage bag." Fluid drain bags were well-known in the art, including as taught by Rauschenberger, which discloses a "drainage bag" connected to a urinary catheter. (Ex. 1021 at 2:25; Fig. 1; Ex. 1008 at Fig.1.) Doing so would merely involve a simple substitution of one container (a "bottle") for another known type of container (a "bag") to produce predictable results.

268. As Rauschenberger already discloses a urethral catheter attached to a drainage bag, there would have been ample room to provide Serany's closed-system Foley catheter in the place of the closed-system catheter of Rauschenberger. To the extent that Medline argues that there would not be room to accommodate the closed-system Foley catheter of Serany, the tray of Rauschenberger could easily be

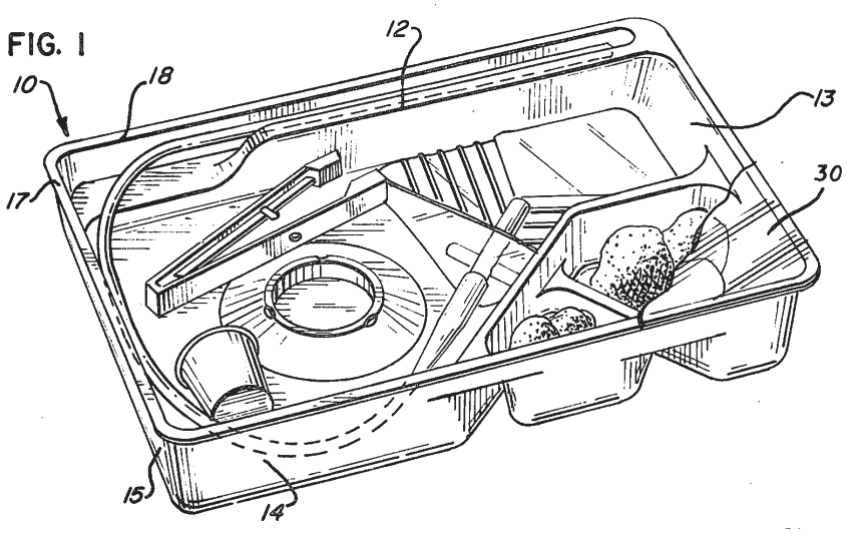
modified (e.g., made wider, longer, or deeper) to accommodate such component givens that it was well-known by a POSA that compartment can be sized to fit the components within, which is a basic principle of medical device packaging.

269. Accordingly, Rauschenberger in view of Serany discloses this claim element.

(c) Limitation 13[c]

270. Rauschenberger in view of Serany discloses a "*single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly*."

271. The equipment of Rauschenberger is stored in a single-layer tray, tray 10, shown in Figure 1 below:



(Ex. 1021 at Fig.1,1:50-61.)

The tray has at least four compartments:

- Channel 21 (which is "adapted to receive a conventional urethral catheter which is positioned within channel 21)

- Main compartment of dish 11 (which stores the "remainder of the catheter," the drainage bag, forceps, and a specimen container)

- Compartments 23 and 24 (which store absorbent pads)

(Ex. 1021 at 1:62-2:27.)

272. Either channel 21 or the main compartment of dish 11 satisfies the requirement of "a second compartment for receiving at least a portion of the medical assembly" because both receive a portion of the catheter assembly. As being a "first," "second," or "third" compartment is an arbitrary designation, I identify here the main compartment of dish 11 as the claimed "first compartment" and channel 21 as the claimed "second compartment for receiving at least a portion of the medical assembly" because it "receive[s] a conventional urethral catheter," and thus meets this limitation. (Ex. 1021 at 1:62-64.)

273. Claim 13 further requires "a first compartment for receiving the first syringe and the second syringe." For the reasons at limitation 13[a], it would have been obvious to include a lubricant and an inflation syringe in the kit of Rauschenberger. Rauschenberger states that: "The catheter is located in groove 21 and absorbent material is located in compartments 23 and 24." (Ex. 1021 at 2:20-22.) This means that the other components, including the lubricant, are stored in the main compartment dish 11 (a first compartment):

> The remaining components [sic.] generally are arranged sequentially from the top of the tray on down in the order: gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container. For purposes of clarity, not all of the components are shown in the drawings.

(Ex. 1021, 1:22-27.)

274. While the "lubricant" of Rauschenberger is not depicted in the Figures, Rauschenberger discloses it being stored in the same location as the forceps, specimen container, and drainage bag, i.e., in the main compartment of dish 11. (*Id.*, 1:22-27, Fig. 1.) When adding an inflation syringe to the kit of Rauschenberger, it would have been obvious to store it with the lubricant in dish 11.

275. *First*, Rauschenberger notes that compartments 23 and 24 are for absorbent pads and channel 21 stores a portion of the catheter, which leaves dish 11 to store the "remaining components." Thus, it would have been obvious to also store the water syringe in dish 11, which could be adapted if necessary (i.e., made larger) to accommodate a water syringe.

276. *Second*, it was known in the art to store like items in the same compartment. For example, Rauschenberger groups multiple absorbent pads in compartments 23 and 24. (Ex. 1021 at 2:20-22; Fig. 1.) Serany groups rayon balls 34 together in a compartment. (Ex. 1009 at 1:57-72; Fig. 6.) The lubricant of Rauschenberger (replaceable with a syringe) and added inflation syringe are like

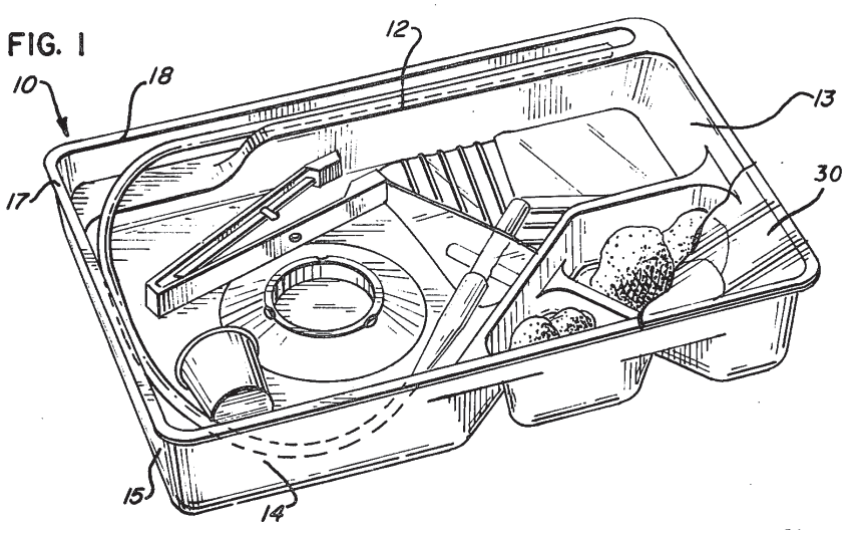
items as they are both syringes and used with the catheter (to lubricate it and inflate its retention balloon).

277. *Third*, it would have been obvious to try grouping the lubricant and water syringe in the same compartment given the finite number of identified, predictable solutions (i.e., storing the syringes in separate compartments or the same compartment) with a reasonable expectation of success.

278. Finally, for the reasons at limitation 13[h], the syringe could be held in place within dish 11 using recesses (a well-known technique) to avoid damaging the other equipment within dish 11 (e.g., the catheter assembly). Accordingly, Rauschenberger in view of Serany discloses this claim element.

(d) Limitation 13[d]

279. Rauschenberger discloses "*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber*." Specifically, Rauschenberger discloses using channel 21 (a lubricating jelly application chamber) to lubricate the catheter: "[g]loves are donned and a lubricant packet is utilized to put lubricant on the catheter in channel 21. The catheter then is rotated within channel 21 to spread lubricant about it insertion end. Ramp section 20 supports the catheter during its rotational movement and minimized the danger of the catheter being dislocated from channel 21." (Ex. 1021 at 2:31-36; Fig. 1.)



280. Rauschenberger allows passage of the catheter (substitutable with a Foley catheter) into the lubricating jelly application chamber formed by channel 11 because "[c]hannel 21 is adapted to receive a conventional urethral catheter which is positioned within channel 21." (Ex. 1021 at 1:62-63.) Specifically, as shown in Figure 1 above, there is an opening between the first compartment (dish 11) and second compartment (channel 21) that allows the passage of at least some of the Foley catheter into channel 21, which is a lubrication jelly application chamber. Indeed, rotating the cheater within channel 21 would mean a portion of the catheter is passed into the lubricating jelly application chamber in use. (Ex. 1021 at 2:31-36; Fig. 1.)

281. I note that the Board found in instituting IPR of claim 21 of '935 Patent that: "We are persuaded, on the present record, that Rauschenberger's disclosure of "rotat[ing the catheter] within channel 21 to spread lubricant about its insertion end"

(Ex. 1111, 2:31–33) is sufficient to teach "pass[ing] at least a portion of the catheter assembly into the contents" (e.g., into the lubricant in the first compartment)." (Ex. 1026 at 16.)

282. Rauschenberger thus discloses this claim element.

(e) Limitation 13[e]

283. Rauschenberger discloses an "*outer packaging disposed about the single layer tray*."

284. Rauschenberger discloses an outer packaging: cover sheet 30. Specifically, Rauschenberger states: "In its packaged configuration the catheterization implements are placed in tray 10 as shown in FIG. 1 and sealed with a cover sheet 30 about flange 17. Cover sheet 30 is formed of conventional peelable lid stock such as coated paper or plastic which is permeable to sterilizing gases." (Ex. 1021 at 2:15-20.) By disposing the cover sheet 30 "about flange 17," the outer packaging of Rauschenberger is disposed about the single layer tray. Indeed, a POSA would understand that the cover sheet 30 was disposed about the single level tray as that would be necessary to keep the components within sterile. (*Id.*)

285. I note that I do not understand limitation 13[e] to require the outer packaging to be disposed about the entire surface area of the tray (as with a bag), but rather to be disposed about the tray sufficient to seal the contents within in a sterile manner, which Rauschenberger's cover sheet 30 accomplishes, as noted above, by

being disposed about the flange of the tray. This is consistent with both the plain meaning of an "outer packaging" and "disposed about." Further, the '219 patent expressly states that the claimed "outer packaging" is not limited to a bag: "In FIGS. 30 and 37, the outer packaging material is a thermally sealed bag 2902. It will be understood that this outer packaging is but one embodiment of the various packaging materials that can be used in accordance with embodiments of the invention." (Ex. 1001 at 17:57-61.)

286. Nonetheless, were Medline to argue that Rauschenberger does not expressly disclose this limitation then, Rauschenberger in view of Serany discloses an "*outer packaging disposed about the single layer tray*." Specifically, discloses a Foley catheter tray "encased within an envelope 16." (Ex. 1009, 1:42-45; 1:60-72.):

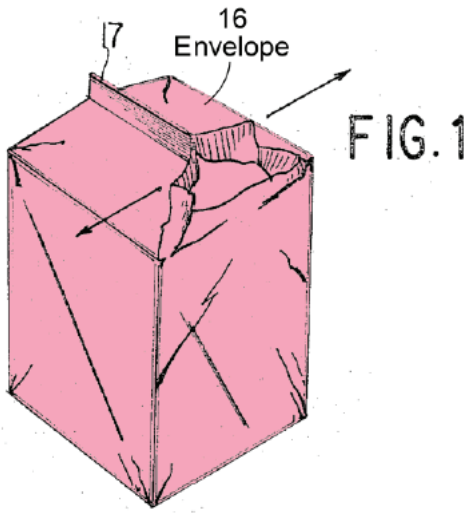


FIG. 1

287. The bag 16 of Serany performs the same function as Rauschenberger's cover sheet 30 as they both seal sterile equipment within the tray. Specifically,

Serany's "envelope 16 seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope." (Ex. 1009 at 1:63-72.) Rauschenberger's cover sheet 30 "is permeable to sterilizing gases," and thus performs the same function. (Ex. 1021 at 2:15-20.) Thus, it would have been obvious to substitute Rauschenberger's cover sheet 30 with Serany's envelope 16 as this is a simple substitution of one known element (a cover sheet) for another (a bag) to yield predictable results (maintain the sterility of components inside a urinary catheter kit). Serany's bag can be "cuffed as shown in FIG. 2 to serve as a waste receptacle," which provides motivation to use Serany's bag in place of Rauschenberger's cover sheet 30, which would be incapable of being used in such a manner. (Ex. 1009 at 1:70-72; Fig. 2.)

288. Accordingly, Rauschenberger discloses this claim element. Rauschenberger in view of Serany also discloses this claim element.

(f) Limitation 13[f]

289. Rauschenberger in view of Serany discloses "*one of the first syringe or the second syringe contains lubricating jelly; another of the first syringe or the second syringe contains water*."

290. For the reasons at limitation 13[a], it would have been obvious to substitute Rauschenberger's lubricant packet with a lubricant syringe and add the

inflation syringe of Serany (which includes sterile water) to the kit of Rauschenberger. (Ex. 1009 at 3:6-10.)

291. Accordingly, Rauschenberger in view of Serany discloses this claim element.

(g) Limitation 13[g]

292. Rauschenberger in view of Serany discloses *"the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure*." Rauschenberger discloses catheterization equipment arranged "sequentially from the top of the tray on down" in the order in which it would be drawn out of the tray and used. I have added numbering in brackets to the equipment described below for ease of reference:

> The remaining components [sic.] generally are arranged sequentially from the top of the tray on down in the order: [1] gloves, [2] lubricant, [3] antiseptic solution, [4] fenestrated drape, [5] forceps, [6] drainage bag and [7] specimen container.

(Ex. 1021, 2:22-27.)

293. After describing this equipment as arranged sequentially, Rauschenberger describes the catheterization process as occurring by using the equipment in the same sequence in which it is arranged, which I have illustrated by again adding numbers in brackets for ease of reference: "**[1] Gloves** are donned and

a **[2] lubricant** packet is utilized… After the catheter has been lubricated, **[3] antiseptic solution** is applied to the absorbent pads… Then the **[4] fenestrated drape** is removed from tray 10.. Next the patient is cleansed with the saturated absorbent pads by holding with the **[5] forceps**…. The patient is catheterized and the urine collected in the **[6] drainage bag**. While the urine is being collected, the **[7] specimen container** is opened…." (Ex. 1021 at 2:30-60 (emphases added).)

294. Thus, when adding a water syringe to Rauschenberger, it would have been obvious to also arrange water syringe sequentially in the order in which it used and drawn out of the catheter kit during the procedure in view of Rauschenberger arranging the other equipment in the tray in its order of use. (Ex. 1021, 2:22-60.) For example, it could be arranged below (or to the left of) the lubricant syringe as the catheter must be lubricated before it is inserted and the retention ballon inflated with the water syringe. This would also be an affordance because it provides a strong clue to the user as to the proper order of use of the syringes.

295. It was also well-known in the art to arrange components in a catheterization kit in their order of use. Specifically, Serany teaches a Foley catheter kit where "provides the convenience of having all the components arranged in logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:30-35.) Serany also discloses providing "components in their preferred order of use" and "proper order of use." (Ex. 1009. at 1:9-12; 1:23-25.) Thus, it would have

been obvious in view Serany to arrange the syringes in the tray of Rauschenberger their order of removal and use, and Serany provides motivation to do so. This applies a known technique (arranging components in their order of use) to a known device (a catheter kit) ready for improvement to yield predictable results (arranging items in "a logical step-by-step order to facilitate the nurses or physicians task").

296. Accordingly, Rauschenberger in view of Serany discloses this claim element.

(h) Limitation 13[h]

297. Rauschenberger in view of Serany discloses "*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*."

298. Rauschenberger discloses "a circular recess for receiving and holding a upright specimen container" where the specimen container may be placed after a sample is collected. (Ex. 1021 at claim 1; Fig. 1; 2:55-63.) Recess 26 is shown in Figure 2 below:

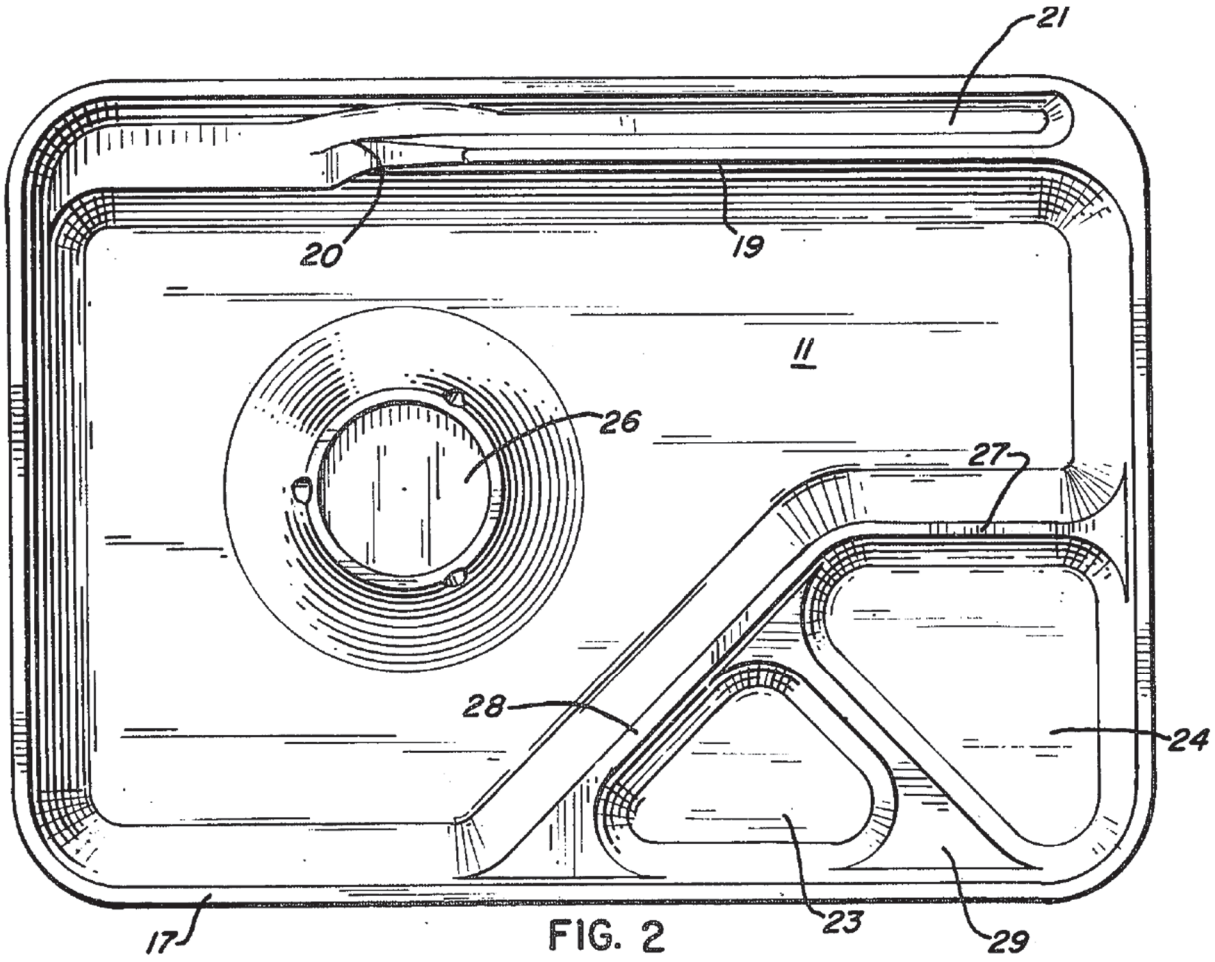


FIG. 2

299. Rauschenberger does not provide any specific mechanism to hold other equipment such as the added syringes in place within the first compartment. The syringes could move during shipment of the tray, which could risk damaging the syringes or the other equipment disposed within the first compartment, especially the catheter.

300. A known technique to prevent syringes from moving during shipping is to define one or more contours of a compartment to accommodate a syringe and its flange—thus holding the syringe in place as well as making it easier to grasp the

syringe. Specifically, Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a "so that it may be easily grasped," and indentations 44d to accommodate the "flange or finger grip 45c of the syringe." (Ex. 1009 at 3:6-22 (emphasis added).) Storing the syringe in this manner "hold[s] the syringe against lateral movement in its stored condition." (Id. at 3:15-16.) Depression 44 is shown in Figure 7 below:

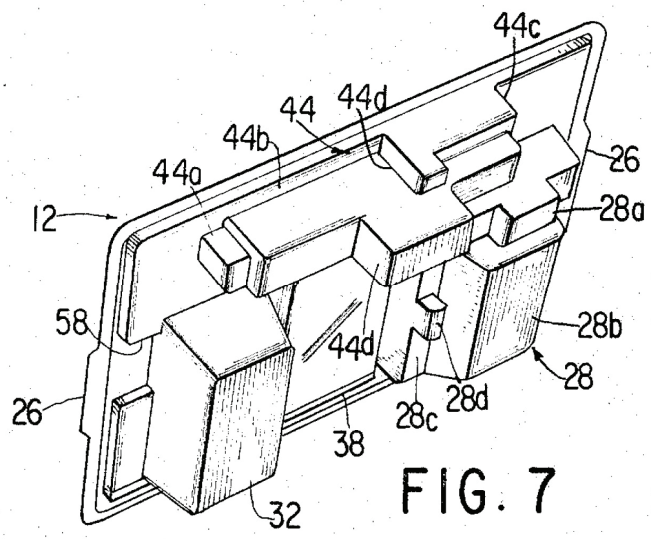


FIG. 7

301. It would have been obvious in view of Serany to add contouring to the first compartment of Rauschenberger to hold the syringe flange of one or more of the first and second syringes such that they do not move during shipping and can more easily be grasped. For example, the tray could be contoured to include a recess (similar to existing recess 26 of Rauschenberger) but shaped to hold the syringes in place instead of the specimen cup. This applies a known technique (contouring to

hold a syringe flange) to a known device (a catheter kit with syringes) ready for improvement to yield predictable results (preventing movement of the syringes during shipping and allow for easy grasping of the syringes.)

302. Accordingly, Rauschenberger in view of Serany renders claim 13 obvious.

2. Claim 14

303. Rauschenberger in view of Serany discloses "*wherein the second syringe is attachable to the Foley catheter*." For the reasons at limitation 13[a], it would have been obvious to add an inflation syringe to the kit of Rauschenberger. An inflation syringe only functions by being attached to the inflation port of a Foley catheter as water must be injected into the catheter to inflate the balloon. Thus, "the second syringe" (i.e., the sterile water syringe) "is attachable to the Foley catheter."

304. Serany discloses "The covering 47 on the tip of the syringe 45 is removed and the balloon on the catheter is inflated with the sterile water in the syringe 45." (Ex. 1009 at 3:6-12, 3:49-52.) Disston describes using the water syringe to inflate the catheter balloon and shows the water syringe attached to the Foley catheter inflation portion (valve 12) in Figure 1:

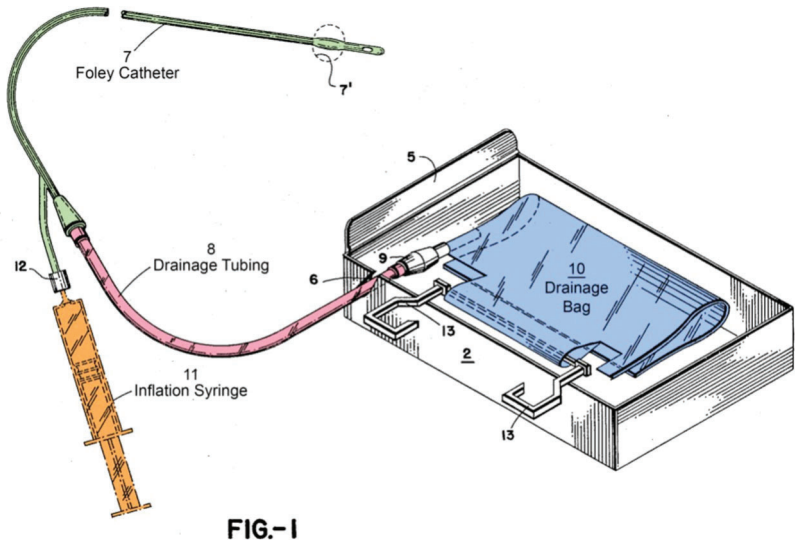


FIG.-1

(Ex. 1008 at Fig. 1; 1:41-53.)

305. Accordingly, Rauschenberger in view of Serany discloses this claim element. Rauschenberger in view of Serany thus renders claim 14 obvious.

F. Ground 5: Obviousness over Rauschenberger, Serany and Salvadori (claims 15-16)

1. Claim 15

306. Rauschenberger in view of Salvadori discloses "*wherein the single layer tray comprises a third compartment containing one or more swabsticks*." Rauschenberger discloses a third compartment—either compartment 23 or 24, which "are adapted to hold absorbent pads separately from each other." (Ex. 1021 at 2:5-7; Fig. 1.)

307. It was well-known to include equipment for cleaning the patient such as an absorbent material along with means to grasp the absorbent material. (Ex. 1009, 1:12-16; 3:4 (disclosing forceps and rayon ballons); Ex. 1021, 2:43-57 (disclosing

forceps and absorbent pads); Ex. 1010, 2:66-3:10 (disclosing forceps and balls); (Ex. 1009, 1:12-16; 3:4; Fig. 1 (disclosing swabsticks).) The absorbent material (a ball, swab, or pad) is used to clean the patient's genitals, typically after cleansing solutions are poured on the absorbent material. Rauschenberger discloses applying "antiseptic solution" to the "absorbent pads" and using forceps to hold the pads to clean the patient: "the patient is cleansed with the saturated absorbent pads by holding the forceps.) (Ex. 1010 at 2:43-51.) Serany provides a similar teaching using rayon balls and forceps. (Ex. 1009 at 2:60-65; 3:45-48.) In the case of swabsticks, the cleansing material is often pre-applied, i.e., pre-saturated.

308. Salvadori teaches a "urethral catheter kit or tray" that includes "swab sticks 60." (Ex. 1013, 1:12-16; 3:4; Fig. 1.)

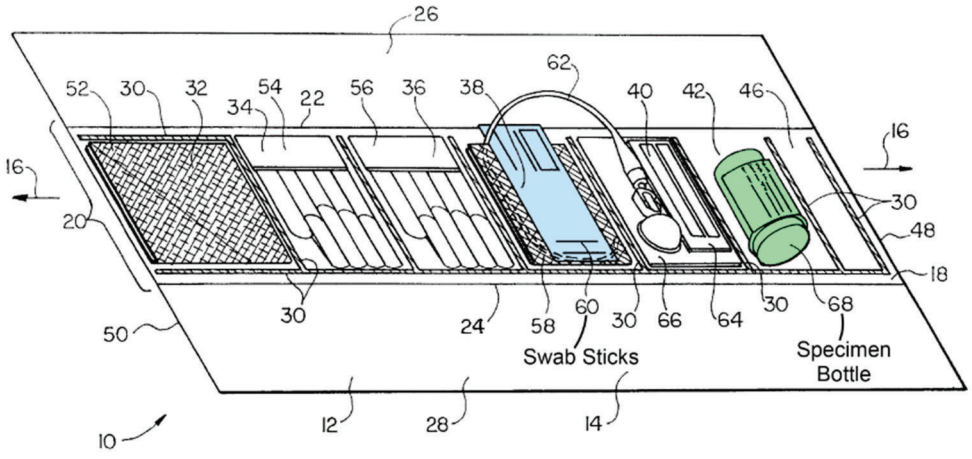


FIG. 1

309. A POSA would have understood these swab sticks to be presaturated with a cleansing material as Salvadori does not disclose the step of pouring a

cleansing material on the swab sticks or a cleansing material stored in its kit. (Ex. 1009.)

310. Thus, as of the time of the invention, the two common forms of equipment to clean a patient's genitals were (1) forceps and balls or pads and (2) swabsticks. Notably, a swabstick merely provides a handle attached to an absorbent material (a swab) as opposed to using forceps to pick up the absorbent material.

311. In view of Salvadori, a POSA would have been motivated to substitute Rauschenberger's absorbent pads, forceps with Salvadori's swabsticks as these items are used to perform the same function: cleaning the patient's genitals. This is a simple substitution of one known device (forceps, antiseptic solutions, and absorbent pads) for another (swabsticks) to yield predictable results. The inclusion of a swabsticks in the catheterization kit of Rauschenberger also involves the use of a known technique (provision of swab sticks) to a known device (a urethral catheter kit) ready for improvement to yield predictable results (providing swab sticks to allow the practitioner to clean the patient before insertion of the Foley catheter).

312. A POSA would have further been motivated to include swabsticks over the other available options because a swabstick is easier to manipulate than forceps. Specifically, a clinician could inadvertently drop a ball or pad if they do not maintain constant pressure with the forceps to grasp the ball/pad, but this is less likely to occur with a swabstick, which can simply be picked up by its handle.

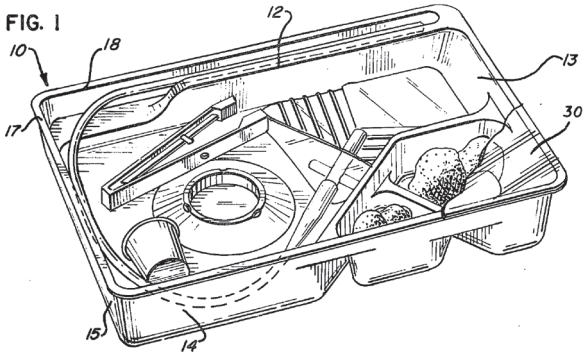
313. I note the Board has concluded in the Previous IPRs that "testimony from both parties' experts reveals that cleaning the insertion point on the patient's body before catheterization is desirable and that swabs and cotton balls are interchangeable for that purpose." (Ex. 1015 at 26-27.) Likewise, swabs are interchangeable with absorbent pads.

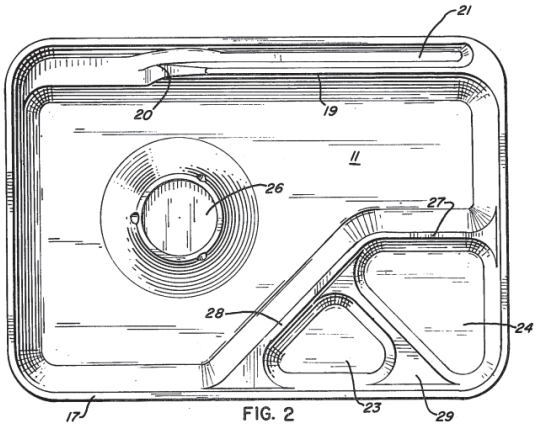
314. When replacing Rauschenberger's cleansing materials with swabsticks, it would have been obvious to store the swabsticks (which are packaged together in a packet as shown in Figure 1 of Salvadori) in compartment 23 or 24 (either of which is a third compartment). Those compartments are already designated as storing absorbent pads, which perform the same cleansing function as swabsticks, and thus there would be a reasonable expectation of success in doing so. For example, there would have been a motivation to store the swabsticks in compartment 24, which is larger than compartment 23, such that used swabsticks could be placed in compartment 23 as the procedure is performed. (Ex. 1021 at 2:49-55 (discussing placing used absorbent pads in compartments 23 and 24).) Alternatively, it would have been obvious to combine 23 and 24 into a single compartment to store the swabsticks since they are packaged together as opposed to the individual absorbent pads.

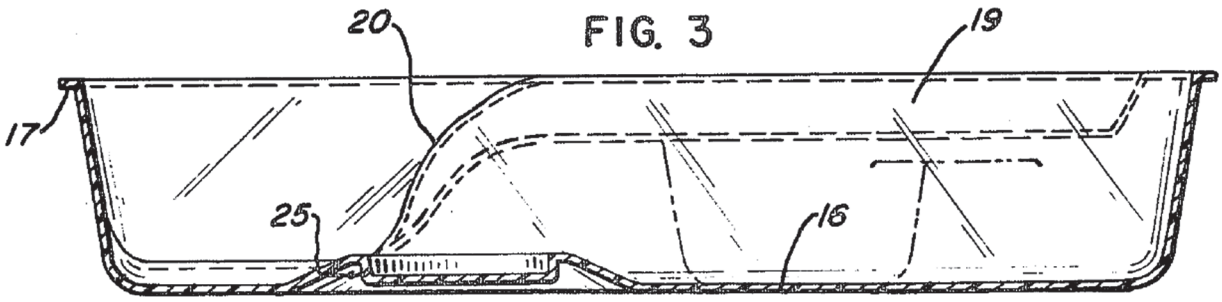
315. Accordingly, Rauschenberger in view of Salvadori discloses this claim element. Rauschenberger in view of Serany and Salvadori thus renders claim 15 obvious.

2. Claim 16

316. Rauschenberger discloses "wherein a boundary surface defines the lubricating jelly application chamber." "Tray 10 is formed with a dished portion 11 defined generally by outside walls 12, 13, 14, 15 and 18 and bottom wall 16." (Ex. 1021 at 1:50-52. Thus, as shown in Figures 1-3 below, the lubricating jelly application chamber (channel 21) is formed by the boundary surfaces of the tray, including at least walls 12 and 18: "Wall 12 … cooperates with wall 18 to form the channel 21 in that portion of dish 11." (Ex. 1021 at 1:59-61.) Specifically, these are boundary surfaces of the tray because wall 12 as well as the bottom surface of channel 21 (the lubricating jelly application chamber) delineate the boundaries of the tray.







317. Accordingly, Rauschenberger discloses this claim element. Rauschenberger in view of Serany and Salvadori thus renders claim 16 obvious.

G. Ground 6: Obviousness Over Solazzo, Serany, Disston, and Imai (claims 13-14)

1. Independent Claim 13

(a) Limitations 13[p] and 13[a]

318. Solazzo discloses "*A medical procedure kit, comprising: a first syringe and a second syringe*."

319. Solazzo discloses a "medical procedure kit:" "an ergonomic urological catheterization/irrigation tray" with equipment for performing both Foley catheterization and irrigation procedures. (Ex. 1005 at 2:34-35, 3:12-24, Figs. 1, 8.) Solazzo discloses a "medical procedure kit" with the equipment stored in a single layer tray having multiple compartments as shown in Figures 1 and 8 below:

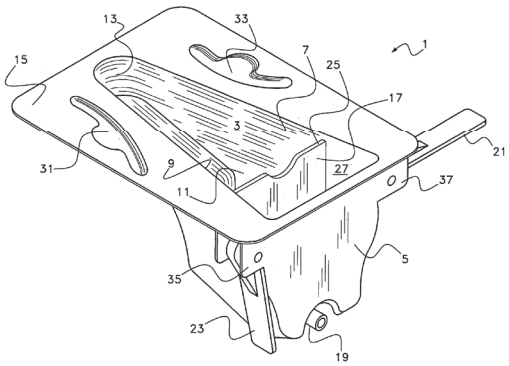


Fig. 1

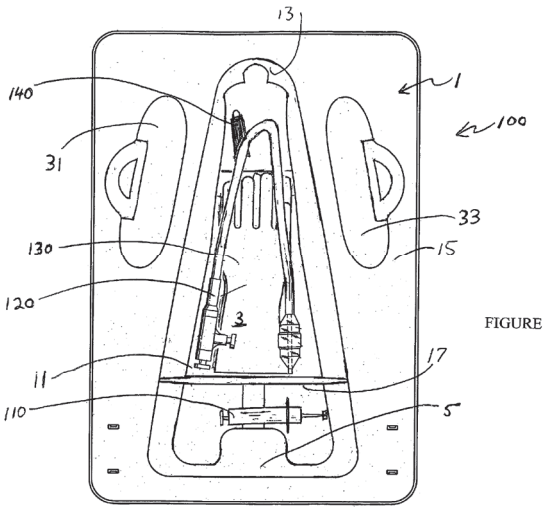


FIGURE 8

(Ex. 1005, Abstract; Figures 1, 8.)

320. Solazzo teaches a tray that may be used for both catheterization and irrigation procedures. (Ex. 1005 at 2:35-36.) I understand from Dr. Yun that a catheterization procedure is the insertion of a urethral catheter (such as a Foley catheter using well-known steps such as lubricating the catheter and inflating the retention ballon of the Foley catheter with an inflation syringe. (Ex. 1003 ¶¶ 43-60.) These steps are described by Solazzo. (Ex. 1005 at 4:41-48.) I understand from Dr. Yun that an irrigation procedure is a procedure that is done through an inserted Foley catheter to flush the bladder to remove clots. The Solazzo patent includes both catheterization equipment such as lubrication and an inflation syringe as well as an "irrigation syringe. (Ex. 1005 at 3:15-24.) Solazzo is also titled "Ergonomic Urological Catheterization/Irrigation Tray." Solazzo further states: "The present

invention relates to an ergonomic urological catheterization/irrigation tray." (Ex. 1005 at 2:35-36.)

321. The tray of Solazzo includes four compartments: compartment 3, compartment 27, compartment 31, and compartment 33. (Ex. 1005 at Figures 1 and 8.) "Optional divider wall 17 creates two separate compartments." (Ex. 1005 at 4:15-16.) Specifically, "a first compartment" ("compartment 27") and a second compartment ("recessed area 3") are formed in the tray via divider wall 17. (Ex. 1005, 2:61-63; 4:15-20; Figures 1, 3. 8)

322. "[T]he kit [of Solazzo] includes: (a.) the tray described above; (b.) a Foley catheter; (c.) a urinary tract lubricant; (d.) surgical gloves; (e.) an inflation syringe for inflation of a catheter with fluid (f.) irrigation syringe; (g.) evacuation tubing; and, (h.) antiseptic solutions." (Ex. 1005 at 3:15-24.) Certain of this equipment is shown placed in the tray in annotated Figure 8 below:

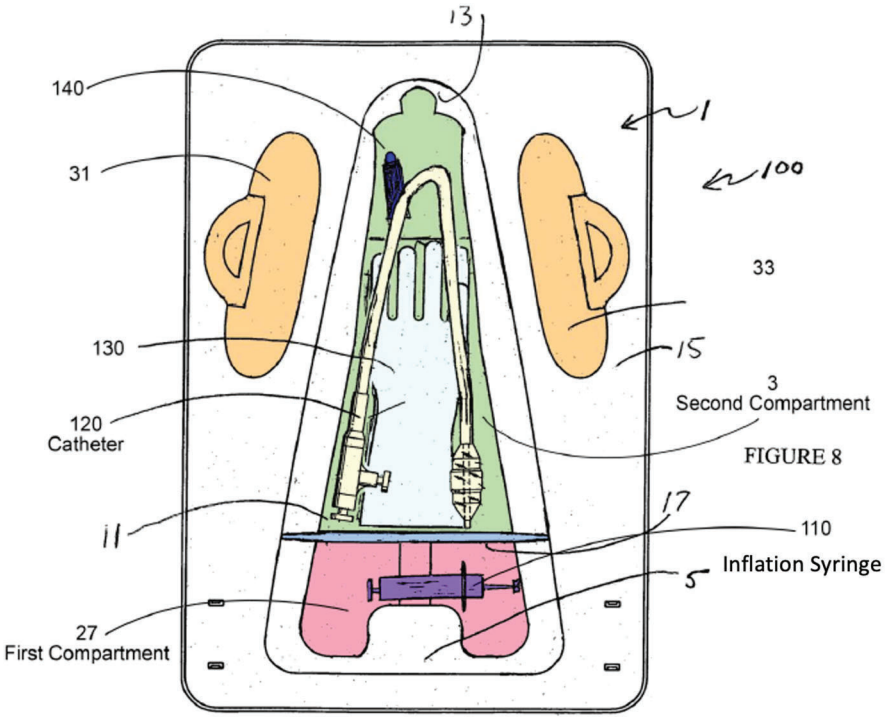


FIGURE 8

323. Solazzo thus discloses "*a first syringe and a second syringe*" because it includes both an inflation syringe and irrigation syringe. (Ex. 1005 at 3:15-24.) Additionally, for the reasons below, it would have been obvious to substitute Solazzo's lubricant tube with a lubricant syringe. Solazzo's kit includes "a tube of lubricant fluid 140" disposed in compartment 3. (Ex. 1005, 4:41-46; Fig. 8.) It would have been obvious to provide a lubricant syringe in place of the tube. A POSA would understand that lubricant could come in a variety of dispensers (a tube, a syringe, a packet, etc.). A syringe also provides a medical device connection via a Luer slip or Luer lock connection for use with caps, is less likely to leak or puncture when stacked with other rigid medical devices, and provides a controlled and measurable dispensing of lubricant. And a syringe is a well-known instrument as

shown by Solazzo which includes multiple syringes: an inflation and irrigation syringe.

324. Providing lubricant in a syringe as part of a Foley catheter kit was also well-known in the art. The Nursing Standard discloses an "all-in-one Foley tray" with a "syringe of urethral lubricant." (Ex. 1019 at 52.) A Catheterization Video shows a syringe provided inside a Foley catheter tray that is filled with lubricant. (Ex. 1020 at 2:43-2:60.)

325. A POSA would further have been motivated to switch from a tube of lubricant to a syringe of lubricant because dispensing lubricant of the syringe may require less effort or offer more control than a tube—allowing for the efficient lubrication of the catheter. I also understand from Dr. Yun that a syringe allows for dispensing lubricant directly into the male urethra to deliver the maximum possible amount of lubricant to the patient (as compared to running the catheter through a pile of lubricant where some is wasted). (Ex. 1003 ¶ 49.) This method is not possible with other lubricant containers. This is a simple substitution of one known element (a lubricant tube) for another (a lubricant syringe) yielding predictable results. The PTAB previously found it would have been obvious to substitute Solazzo's lubricant tube with a syringe of lubricant:

> Although Solazzo describes placing lubricant in tube 140 rather than a syringe, Petitioner persuasively argues that an ordinarily skilled artisan would have considered it to be obvious to place the lubricant in a syringe as a known

> substitute used for a known purpose. Pet. 39–40 (citing Ex. 1002 ¶¶ 160–162). Ms. Chiappetta, Patent Owner's nurse practitioner expert, testified that her "preference would be a syringe . . . it's easier to get the lubricant out of it." Ex. 1073, 60:23–61:24.

(Ex. 1023 at 17-18.)

326. Accordingly, Solazzo in view of Serany and Disston discloses this claim element.

(b) Limitation 13[b]

327. Solazzo in view of Serany and Disston discloses "*a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*."

328. Solazzo discloses a medical assembly (a Foley catheter 120) disposed in the second compartment. (Ex. 1005, 3:14-24, 4:41-46; Fig. 8.) In Figure 8, the balloon of the Foley catheter is depicted as well as Y-connector to allow for the inflation of the balloon. (Solazzo at 3:17; 4:41-46; Fig. 8.)

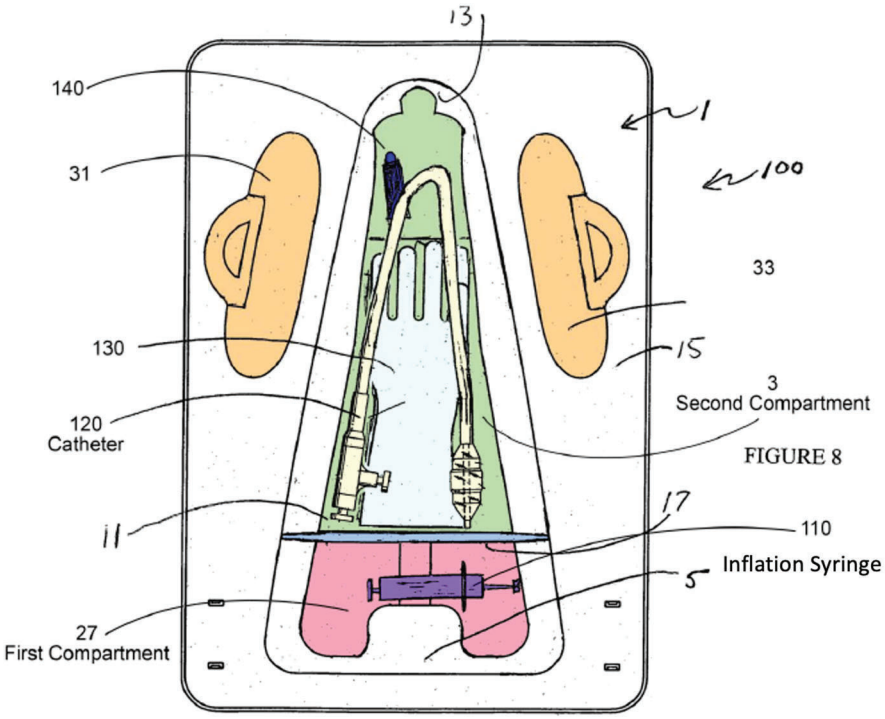


FIGURE 8

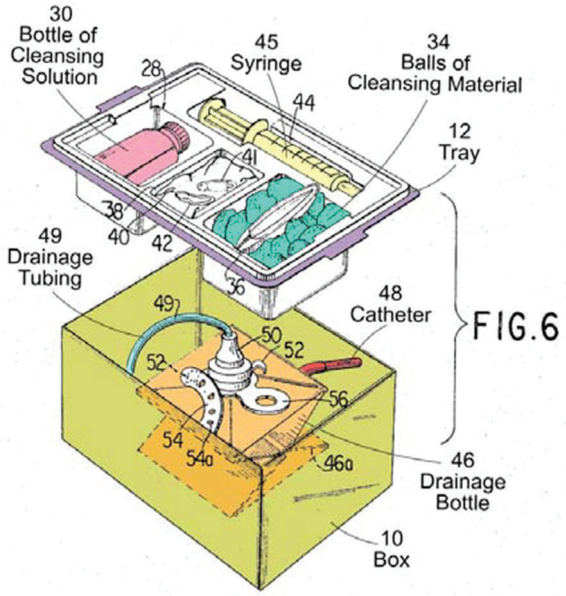
329. Solazzo also discloses "evacuation tubing," and notes that "[d]rain 19 may be connected to flexible tubing and into a receiving receptance". (Solazzo at 3:15-24; 4:10-15.)

330. Solazzo discloses a "urological catheterization/irrigation tray" that can be used for perform both catheterization and irrigation procedures—the tray may be used to "evacuate the bladder of its contents, urine and/or clots." (Ex. 1005 at 4:26-33.) I understand generally speaking that evacuating the bladder of its urine refers to a urinary catheterization procedure and evacuating the bladder of clots refers to an irrigation procedure.

331. A Foley catheter is an indwelling catheter that includes a balloon to retain the catheter in the patient for longer periods of time. Solazzo discloses the

ability to "discharge or be relieved into the tray." (Ex. 1005 at 2:42-46.) However, the discharge of urine into an open-topped tray is not a long-term solution for an indwelling Foley catheter. This instead requires a closed container such as a drainage bag, which is disclosed by Serany. Although Solazzo does not expressly disclose a closed-system Foley catheter (i.e., a catheter that is pre-connected to a drainage bag via tubing, such systems were well-known in the prior art as shown, for example, by Bard's Disston and Serany patents.

332. Serany discloses a closed-system Foley catheter, which is a medical assembly that "comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter." Specifically, Serany discloses a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use" and "[t]he catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex. 1009, 3:23-36; Fig. 6. Thus, Serany expressly describes its drainage tubing as "coiled," and that it would also need to be coiled to fit within the tray of Solazzo given that such equipment is typically much longer (several feet) than the length of a typical medical device storage kit.



333. While Serany refers to catheter as being connected to a "drainage bottle," it describes the "bottle" as being made out of a "flexible plastic material" that can be collapsed inside the box. (Ex. 1009, 3:26-32.) A POSA would understand Serany to therefore also teach a drainage/fluid bag.

334. Disston discloses a "medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter." Specifically, Disston discloses "a pre-assembled catheter-tube-bag assembly," including Foley catheter 7, drainage tube 8, and drainage bag 10. (Ex. 1008 at 2:15-23, Fig. 1.)

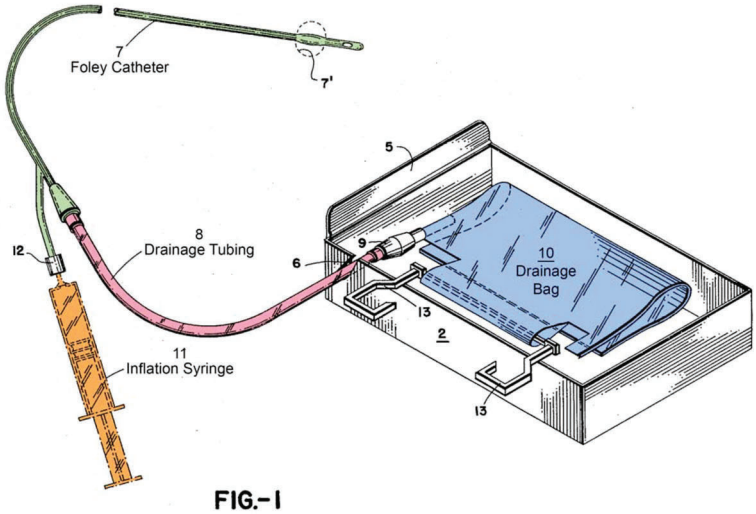


FIG.-1

335. To the extent Medline argues that Serany does not teach a bag, it would have been obvious to substitute the "bottle" of Serany with the "bag" of Disston. Doing so would merely involve a simple substitution of one container for another known type of container to produce predictable results. Containers for storing liquids such as bottles or bags were also known to a POSA to be interchangeable as their selection depending on the application and fluid being contained (with urine being capable of held in either a bottle or bag as taught by Serany and Disston), as well as cost targets and shipping/storage considerations.

336. It would have been obvious to substitute the closed-system Foley catheter of Serany in place of the Foley catheter of Solazzo. This is a simple substitution of one element (a closed-system Foley catheter) for another (a Foley catheter) to yield predictable results. Specifically, this could be accomplished

simply by substituting Solazzo's Foley catheter for Serany/Disston's closed-system Foley catheter. Alternatively, Serany/Disston's drainage bag and tubing could be added to the kit and pre-connected to Solazzo's Foley catheter.

337. In view of Serany and Disston, a POSA would have been motivated to include a closed-system Foley catheter (including "a coiled tubing coupled between a fluid drain bag and a Foley catheter") in the second compartment 3 of Solazzo. First, Serany and Disston teach pre-connected systems that are "ready for use"—eliminating the need to obtain additional components. As explained by Serany, "[i]n using this package, the nurse or physician is assured that it will not be necessary to interrupt the procedure to search for missing items necessary to complete the job or to question the sterility of the items being used." (Ex. 1009 at 1:21-23.) This therefore applies a known technique (a closed-system Foley catheter that is ready for use as taught by Serany) to a known device (a Foley catheter kit as taught by Solazzo) ready for improvement to yield predictable results.

338. Second, it was known in the art that closed-system Foley catheters reduce the risk of infection. (Ex. 1019, 51-52; Ex. 1009 at 1:31-32, 3:23-44, Fig. 6.) For example, the Nursing Standard article states: "Catheters should be connected to a sterile catheter bag or valve, creating a closed system." (Ex. 1019, 51-52.) It emphasizes the importance of a "closed system" catheter in reducing CAUTIs. (Ex. 1019, 51-52.) Specifically, the article explains that CAUTIs drop by over 80% when

using a closed system, for example, as disclosed in the Serany and Disston. (Ex. 1019 at 51.) Notably, Nursing Standard cites to an article from 1964 when making this point. Serany, which discloses a closed-system Foley catheter, was filed in 1965 and notes that "[a]nother object of this invention is to provide a catheterization package which reduces the incidence of infection." (Ex. 1009 at 1:31-32, 3:23-44.) Thus, in view of Serany, a POSA would have been motivated to include a closed-system Foley to "reduce[] the incidence of infection."

339. Placing the closed-system Foley catheter in Solazzo's tray does not eliminate the catheterization or irrigation features of the tray. To the contrary, it improves the catheterization feature as described above because a closed-system Foley catheter is superior from the standpoint of both convenience and reducing infection. Nor does it eliminate the irrigation feature of the tray. I understand from Dr. Yun that it is not typically known in advance that irrigation is necessary and that it is often discovered only after catheterizing the patient when the clinician observes the urine does not run freely (likely due to clotting). (Ex. 1003 ¶¶ 71-72; *see generally* Ex. 1003 ¶¶58-87.) At this point, the catheter can be irrigated by simply detaching the Foley catheter from the tubing, which is a simple and quick operation, and then inserting the irrigation syringe into the Foley catheter to flush it. (*Id.*) Thus, a POSA would understand that it is better to start with a closed-system and detach

the tubing if irrigation proves necessary rather than add a closed-system (i.e., add tubing and a drainage bag) when irrigation is not necessary.

340. Solazzo, Serany, and Disston are analogous references as both are Foley catheter kits that store similar medical device equipment, including a Foley catheter, lubricant, an inflation syringe, gloves, and tubing. (Ex. 1005 at 3:15-25; Ex. 1008 at Fig. 1; 2:15-60; Ex. 1009 at Fig. 6; 3:1-45.) Thus, there would have been a reasonable expectation of success in combining these references.

341. Finally, I note my understanding that the Board previously found an identical claim limitation obvious in view of the same prior art. (Ex. 1015 at 15-18.) Additionally, I understand during previous IPRs that that the Board thoroughly considered (but rejected) Medline's numerous arguments regarding why Solazzo and Serany were allegedly incompatible or why a POSA would not have been motivated to add a closed-system Foley catheter to Solazzo. (IPR2019-00208, Paper 57 (Ex. 1023) at 20-22.)

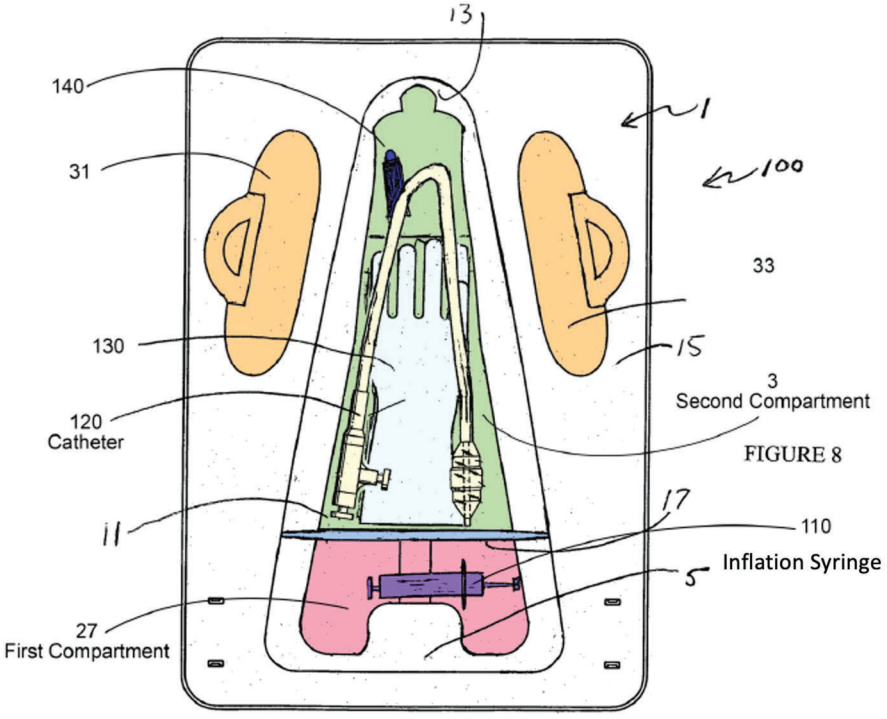
342. Accordingly, Solazzo in view of Serany and Disston discloses this claim element.

(c) Limitation 13[c]

343. Solazzo in view of Serany discloses "*single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly*."

344. For the reasons at claim 13[b], Solazzo in view of Serany discloses "*a second compartment for receiving at least a portion of the medical assembly*."

345. As shown in Figure 8 below, compartment 27 is a "first compartment for receiving syringes" as it stores at least inflation syringe and compartment 3 is "a second a second compartment for receiving a medical assembly" as it store at least Foley catheter 120. (Ex. 1005, 2:48-51, 3:15-24; 3:52-57, Figure 1 and 8.)



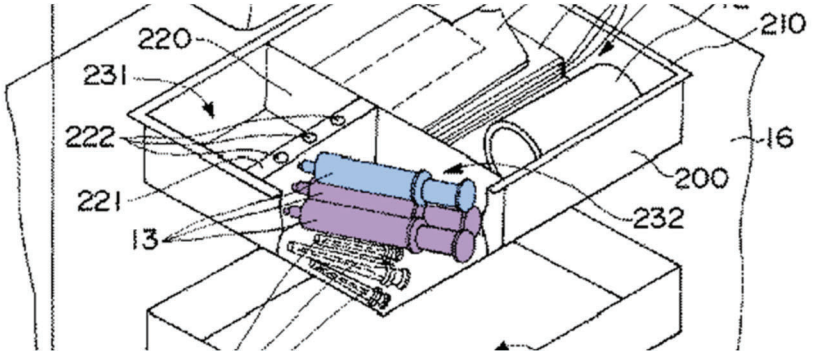
346. Solazzo discloses "[t]he kit includes" both "an inflation syringe" and "an irrigation syringe." (Ex. 1005, 3:15-24.) As discussed above, compartment 27 of Solazzo holds at least inflation syringe 110. (Ex. 1005, Fig. 8.) The location of the "irrigation syringe" within the tray is not expressly provided as it is not depicted in Figure 8. (Ex. 1005, Fig. 8.) But there are only two locations where it could be

held: first compartment 27 or second compartment 3. It would have been obvious to store the irrigation syringe in compartment 27 because it already holds the inflation syringe, and thus a person of ordinary skill in the art ("POSA") would understand that the compartment is sized to accommodate syringes. *C.R. Bard v. Medline Indus. Inc.*, 2021 WL 3574043, *4-5 (Fed. Cir. 2021) "Although the prior art does not 'expressly' direct a skilled artisan to place two syringes in one compartment, it certainly was well within the possibilities available to him to do so. As the Board acknowledged, a person of ordinary skill had only two options for storing the irrigation syringe: either together with the inflation syringe or apart. And, as Bard's expert testified, among those limited options, a skilled artisan had ample reason to avail himself of the obvious option of placing both syringes in the same compartment.")

347. Solazzo also discloses a "tube of lubricant 140." (Ex. 1005 at 3:15-24, Figure 8.) The lubricant tube is replaceable with a syringe, for the reasons provided at claim 13[a]. It would have been obvious to also store the lubricant syringe in compartment 27 because it already holds the inflation syringe.

348. It was well-known in the art to group like items in the same compartment of a tray. For example, Serany discloses grouping multiple balls of cleansing material in the same compartment. (Ex. 1009, 2:57-61.) Additionally,

Imai discloses grouping three syringes 13 in the same compartment of a catheter tray:



(Ex. 1012 at Figure 1; ¶¶ 0028, 0031.)

349. Solazzo and Imai are also analogous references as both are catheter kits for storing similar medical device equipment, including a catheter and multiple syringes. (Ex. 1005 at 3:15-25; Ex. 1012 at Fig. 1; ¶ 0078.) Thus, there would have been a reasonable expectation of success in combining these references.

350. A POSA would therefore understand that compartment 27 of could hold all three syringes (inflation, irrigation, and lubricant) in a stacked configuration as all three syringes would have similar shapes. For example, if the syringes were stacked (as taught by Imai) as well as arranged in their order of use (as taught by Serany), the lubricant syringe could be placed atop the inflation and irrigation syringes which are used later in the procedure. (Ex. 1009 at 1:23-25, 1:31-35.) In view of Serany and Imai, a POSA would have been motivated to group all three syringes in the first compartment of Solazzo to arrange them in a "logical step-by-

step order to facilitate the nurses or physicians task" as taught by Serany. (Ex. 1009 at 1:23-25, 1:31-35)

351. Finally, it would have been obvious to try grouping the syringes in the same compartment given the finite number of identified, predictable solutions (i.e., storing the syringes in separate compartments or the same compartment) with a reasonable expectation of success.

352. I note my understanding that the Federal Circuit and Board have previously found an identical claim limitation obvious in view of the prior art presented in this petition. (Ex. 1015 at 15-17); *Bard*, 2021 WL 3574043, at *4.

353. Accordingly, Solazzo in view of Imai discloses this claim element.

(d) Limitation 13[d]

354. Solazzo discloses "*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber*."

355. Solazzo discloses lubricating wells, which are a "lubricating jelly application chamber." Specifically, Solazzo discloses "[o]ptional Foley catheter lubricating wells 31 and 33 [which] are available for right handed and left handed users so that lubricating material could be applied to the catheter or other insertion device by filling the well with lubricant and then sliding the device through the lubricant in the well." (Ex. 1005 at 4:21-25; Figs. 1, 3, 8.) In order to lubricate the Foley catheter in Solazzo's lubricating wells they must allow passage of at least

some of the Foley catheter into a lubricating jelly application chamber. Indeed, Solazzo expressly states that they function by "sliding the device through the lubricant in the well," i.e., passing at least at least a portion of the Foley catheter into the wells/chamber.

356. I note my understanding that the PTAB previously found obvious a limitation reciting "the single layer tray comprising a lubricating jelly application compartment" in view of Solazzo. (Ex. 1015 at 24-25.) The Board noted that "Petitioner identifies Solazzo's lubricating wells 31, 33 as the claimed "lubricating jelly application compartment." (*Id.*)

(e) Limitation 13[e]

357. Solazzo in view of Serany disclose "*an outer packaging disposed about the single layer tray*."

358. Solazzo discloses a Foley catheter tray with an open top, which a POSA would understand needs to be packaged for shipping and sale both to hold the components within the tray when it is shipped and to maintain the sterility of components within. Solazzo does not expressly state how the kit is packaged. A POSA would thus turn to well-known solutions for packaging medical device kits, including Foley catheter kits.

359. An extremely well-known solution for packaging medical device kits (including Foley catheter kits) is to fold a wrap around the tray (as discussed in more

detail at claim 19 below) and then seal the tray with an outer packaging, such as a thermally sealed (or heat sealed) bag.

360. Serany discloses its trays are "encased within an envelope 16" (also called "plastic bag 16") as the outer packaging for its Foley catheter tray. (Ex. 1009 at 1:60-72; 3:58-59; Figs. 1-2.) Figure 1 below shows the outer packaging of Serany:

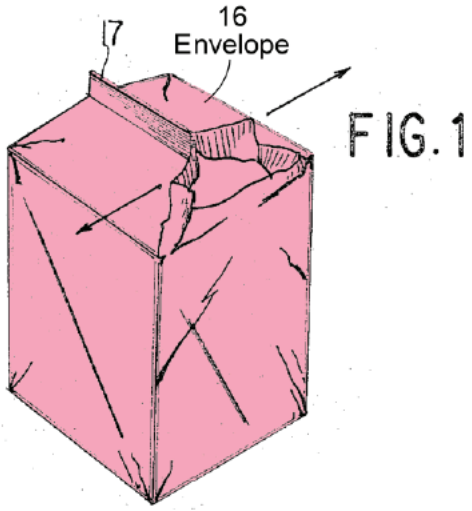


FIG. 1

(Ex. 1009, Fig. 1.)

361. As shown in Figure 1 above, the bag 16 of Serany is disposed about its two trays and when placed around Solazzo would be disposed about its single layer tray. Serany states: "The envelope 16 seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope. The envelope 16, preferably made of a transparent and flexible plastic film, has a heat seal 17 which is adapted to be separated as shown in FIG. 1 to facilitate removal of the contents while maintaining the integrity of the remainder of

the envelope so that it may be cuffed as shown in FIG. 2 to serve as a waste receptacle." (Ex. 1009 at 1:63-72 (emphasis added).)

362. It would have been obvious to a POSA to combine the outer packaging taught by Serany with the tray of Solazzo. A POSA would understand that the tray of Solazzo needs to be packaged for shipping to maintain the components within the tray in their respective compartments and to preserve sterility. For example, Solazzo discloses the kit medical equipment that a POSA would understand needs to be provided sterile such as a Foley catheter, which Solazzo describes being inserted into a patient, as well as "surgical gloves." (Ex. 1005 at 3:15-24; 4:41-48.)

363. Specifically, it would have been obvious to package the tray of Solazzo in the bag 16 of Serany, which a POSA would understand could be adapted to fit the size of the tray of Solazzo. These references are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. Thus, there would have been a reasonable expectation of success in combining Solazzo and Serany. Additionally, the bag of Serany and the tray of Solazzo are both well-known elements and could be combined with each other with each performing the same function as it does separately.

364. There also would have been a motivation to combine these references. Specifically, a person of ordinary skill the art would have understood that the tray of Solazzo needs to be packaged for shipping and sale while maintaining the

components within the tray in their respective compartments and to preserve the sterility of the components provided inside the tray. This also applies known technique (packaging a Foley catheter kit within a bag as taught by Serany) to a known device (a tray for holding a Foley catheter as taught by Solazzo) ready for improvement to yield predictable results (maintaining the sterility of the components of the tray until the package is opened). Serany also teaches using the bag as a waste receptacle, which provides further motivation to package Solazzo in a bag as opposed to other packaging methods that cannot be used in such a manner.

365. Finally, I understand that the PTAB has already concluded that it would have been obvious to add Serany's bag to the kit of Solazzo in IPR proceedings regarding related Medline patents that led to the invalidation of certain claims. (Ex. 1014 at 24.)

366. Accordingly, Solazzo in view of Serany discloses this claim element.

(f) Limitation 13[f] and [g]

367. Solazzo in view of Serany discloses "*one of the first syringe or the second syringe contains lubricating jelly; another of the first syringe or the second syringe contains water*."

368. For the reasons at limitation 13[a] and [c], Solazzo discloses an inflation syringe, which is filled with sterile water. (Ex. 1005, 3:15-24.) A POSA would understand an inflation syringe contains sterile water as that is the fluid

provided in inflation syringes and confirmed by Solazzo which mentions "a syringe prefilled with bacteriostatic water" in the background. (Ex. 1005 at 1:38-42.) Serany also discloses an inflation syringe with "sterile water." (Ex. 1009 at 3:50-51.)

369. For the reasons at limitations 13[a] and [c], Solazzo discloses a tube of lubricant, and it would have been obvious to substitute Solazzo's tube of lubricant with a syringe of lubricant.

370. I understand that the PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 22-23.)

371. Accordingly, Solazzo in view of Serany and Disston discloses this claim element.

(g) Limitation 13[h]

372. Solazzo in view of Serany and Imai discloses "*the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure*." The original configuration of Solazzo presents the lubricant at a higher height than inflation syringe because of the "terraced arrangement" of bottom 11. (Ex. 1005 at 3:63-66; Figs. 2, 8.) Specifically, the lubricant is provided in shallow area 11B and the inflation syringe is provided in low area 11A. (*Id.*)

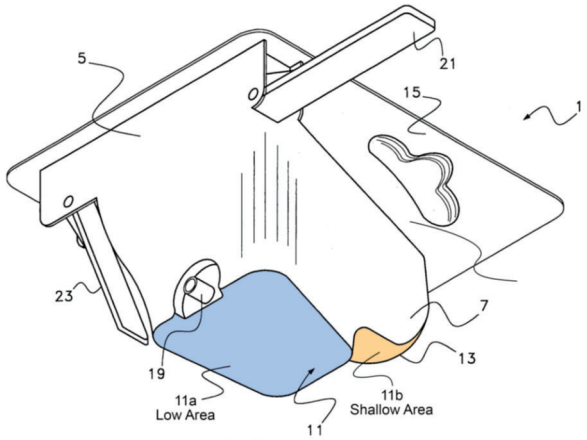


Fig. 2

373. This arrangement (lubricant above the inflation syringe) is consistent with the order of removal (i.e., drawing out) and subsequent use of these components as described by Solazzo: "The gloves being worn by the surgeon, the catheter being lubricated, inserted and then inflated with fluid using the syringe." (Ex. 1005 at 4:46-48.) Indeed, I understand that lubricant is typically used before an inflation balloon (unless a test balloon is inflated) because the catheter must be lubricated before it is inserted. (Ex. 1003 ¶ 53.) If the kit were designed such that a test ballon were inflated, the arrangement of syringes could be reversed.

374. A POSA would have understood that items that are arranged in their order of use are also arranged in the order in which they are removed/drawn out of the tray. Indeed, Disston notes that "contents of the tray portion," including "lubricant, syringe and water packet **are removed and put to their respective intended uses**." (Ex. 1008 at 2:41-45 (emphasis added).) Furthermore, as described

in claims 4-5, Serany—which describes arranging "everything" in "the proper order of use"—discloses "**removing** the bottle 30 of cleansing solution" (stored in the left compartment) so that it can be used by "pouring it over rayon balls" (stored in the right compartment of the tray). (Ex. 1009 at Fig. 6; 2:57-72.) Thus, the items of Serany are stored in their order of use as well as their order of removal/order of drawing out.

375. For the reasons at limitation 13[a] and [c], it would have been obvious to substitute the lubricant tube with a syringe and group both syringes in the first compartment of Solazzo. A POSA would be motivated to maintain this same arrangement of order of use by height when placing lubricant and inflation syringes in compartment 27 because ordering components within a Foley catheter tray in accordance with their use during a catheterization procedure was well-known in the art and convenient for the user. For example, Serany states that "all the components [are] arranged in logical step-by-step order to facilitate the nurses or physicians task." (Ex. 1009 at 1:31-35, 1:23-25.) Serany also discloses providing "components in their preferred order of use" and "proper order of use." (Ex. 1009 at 1:9-12, 1:23-25.) Further illustrating that arranging equipment in their order of use was in a Foley catheter kit was well-known, Disston discloses components that "arranged in such order and position as to be most conveniently available when the container is opened." (Ex. 1008 at 2:15-19.)

376. Finally, it was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order. The term "affordances" was popularized by the author Donald A. Norman in his book "*The Design of Everyday Things*," which was first published in 1988. Mr. Norman states that "affordances" provide "strong clues as to the operation of things."

> Affordances provide strong clues as to the operation of things. Plates are for pushing. Knobs are for turning. Slots are for inserting things. Balls are for throwing or bouncing. When affordances are taken advantage of, the user knows what to do just by looking: no picture, label, or instruction is required.

(Ex. 1025 at 9.)

377. Arranging equipment in a catheter kit, such as syringe in their order of use by stacking them with the first used syringe above the second used syringe is an "affordance" for the user of the kit because the fact that one syringes is on top of another provides a strong clue to the user to use the top syringe first.

378. In view of Serany, it would have been obvious to organize those syringes in the first compartment consistent with their order of use. For example, the lubricant syringe could be positioned above the water syringe because the lubricant step is performed before the Foley catheter is inflated with the water syringe (such as by stacking the syringes as shown by Imai). Alternatively, this

order could be reversed if a test balloon step is performed as that instead requires using the water syringe first.

379. A POSA would have been motivated to arrange the syringes in their order of use in the kit of Solazzo. Serany provides such motivation by teaching components that are "arranged in logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:9-35.) Arranging items in their order of use makes it more likely that the user will perform operations in the correct order as well as quicker to retrieve the correct device. As explained by Serany, "[i]n using this package, the nurse or physician is assured that it will not be necessary to interrupt the procedure to search for missing items necessary to complete the job or to question the sterility of the items being used." (Ex. 1009 at 1:21-23.) Finally, this applies a known technique (arranging components in their order of use) to a known device (a catheter kit) ready for improvement to yield predictable results (arranging items in "a logical step-by-step order to facilitate the nurses or physicians task").

380. The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (Ex. 1014 at 35-36.)

381. Accordingly, the combination of Solazzo in view of Serany discloses this claim element.

(h) Limitation 13[i]

382. Solazzo in view of Serany discloses "*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe.*" As shown in annotated Figure 8 below, Solazzo discloses the syringe barrel rests on a portion of the tray that is contoured to accommodate the flange of the syringe as shown below.

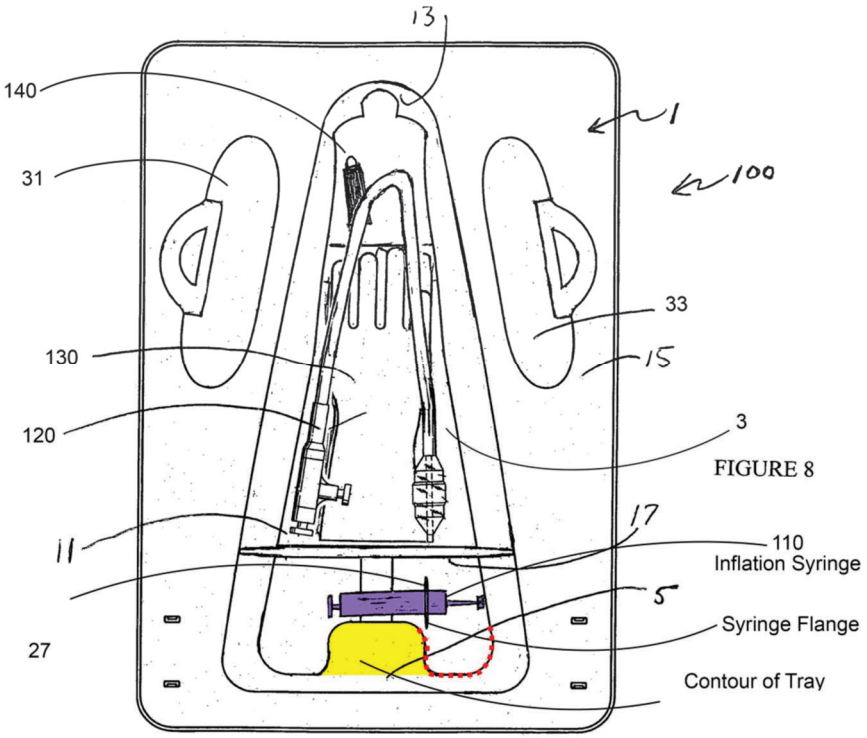


FIGURE 8

383. I understand that Medline has previously argued that a near identical claim limitation should be read to require a contour that restricts movement of the syringes within the tray. Even if this were found to be required by limitation 13[i], Solazzo's contour discloses this claim element because it would restrict movement of the syringe. Specifically, as shown in Figure 8 above, the syringe is placed

precisely such that the flange extends into the area denoted with the red line (which is formed by a contour of the tray). If the syringe were placed to the left of the position showed in Figure 8, it would not fit as shown in Figure 8 because the syringe flange would contact the yellow contoured area. Thus, the first compartment of Solazzo is contoured to accommodate the syringe flange. This contouring would naturally act to prevent movement of the syringe because as shown in Figure 8 one end of the syringe is pressed again the right wall of the tray (preventing the syringe from sliding right). And, if the syringe attempted to slide to the left side of the tray, the flange of the syringe would contact the yellow area, preventing it from sliding left.

384. In a previous IPR proceeding, I understand that the Board declined to determine whether a near identical claim limitation required restricting movement of the syringe. (Ex. 1014 at 28-29.) Regardless, the Board found that "Based on testimony from experts for both parties, we find that the contour in Solazzo's tray that Petitioner identifies does restrict movement to a degree." (Ex. 1014 at 28-29)

385. To the extent Medline argues Solazzo does not expressly disclose this claim element, it would have been obvious to contour the first compartment of Solazzo to hold the syringes in place within the first compartment of the tray.

386. A known technique to prevent syringes from moving during shipping is to contour a tray (e.g., via a depression) to accommodate a syringe and its flange. Adding such a contour both holds the syringe in place and makes it easier to grasp the syringe. Specifically, Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a "so that it may be easily grasped," and indentations 44d to accommodate the "flange or finger grip 45c of the syringe." (Ex. 1009 at 3:6-22.) Serany notes that storing the syringe in this manner "hold[s] the syringe against lateral movement in its stored condition." (*Id. at* 3:15-16.) Depression 44 is shown in Figure 7 below:

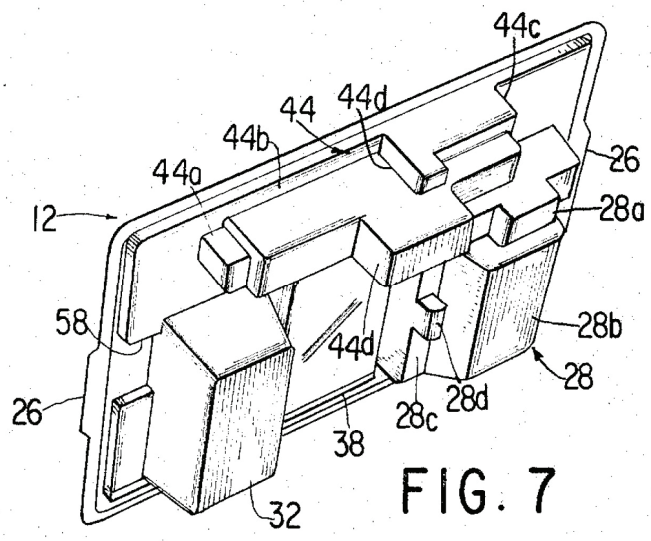


FIG. 7

387. It would have been obvious in view of Serany to add contouring (of modify the existing contouring) of the first compartment of Solazzo to hold the syringe flange of one or more of the first and second syringes such that they do not move during shipping and can more easily be grasped. This applies a known technique (contouring of a compartment of a tray to hold a syringe flange) to a known device (a catheter kit with syringes) ready for improvement to yield predictable results (preventing movement of the syringes during shipping and allow for easy grasping of the syringes.)

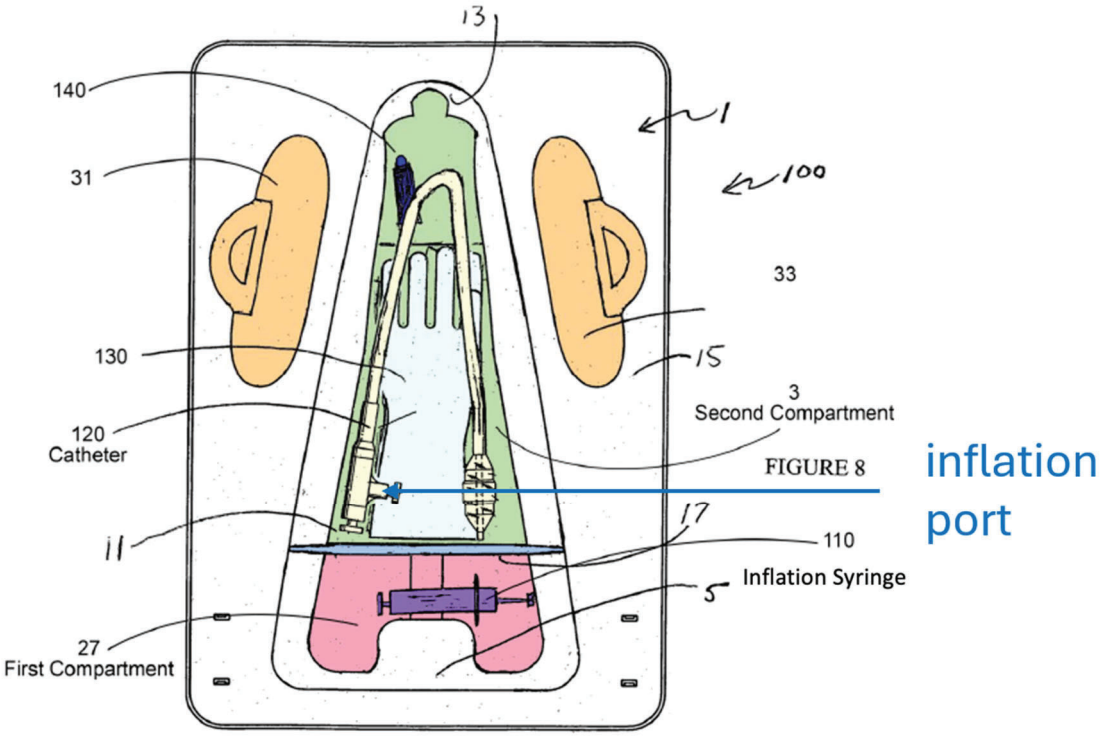
388. A POSA would understand that such contouring could easily be done when manufacturing the tray of Solazzo made using thermoforming or injection molding techniques, either of which could be used to manufacture Numata's tray as discussed at limitation 13[i].

389. In the previous IPR decisions, the Board also concluded that "Petitioner persuasively argues that an ordinarily skilled artisan would have been motivated to incorporate Serany's contours into Solazzo's tray to "allow the syringe to be easily grasped and removed from the tray." (Ex. 1014 at 29.)

390. Accordingly, the combination of Solazzo in view of Serany discloses this claim element. Solazzo in view of Serany, Disston, and Imai thus renders claim 13 obvious.

2. Claim 14

391. Solazzo discloses "*the second syringe is attachable to the Foley catheter*." Specifically, Solazzo discloses: "[t]he kit includes: ... (e.) an inflation syringe for inflation of a catheter with fluid." (Ex. 1005, 1:15-21). Thus, a POSA would understand that for this syringe to inflate the catheter with fluid it must be attachable to the Foley catheter. Indeed, Figure 8 of Solazzo shows a Foley catheter with an inflation port where the inflation syringe is attached to the Foley catheter.



(Ex. 1005 at Fig. 8.)

392. Accordingly, Serany discloses this claim element. Solazzo in view of Serany, Disston, and Imai thus renders claim 13 obvious.

H. Ground 7: Obviousness over Solazzo, Serany, Disston, Salvadori (claims 15-16)

1. Claim 15

393. Solazzo in view of Salvadori discloses "*wherein the single layer tray comprises a third compartment containing one or more swabsticks*."

394. **Swabsticks.** Salvadori discloses "one or more swabsticks disposed within the single layer tray." Specifically, Salvadori teaches a "urethral catheter kit or tray" that includes "swab sticks 60." (Ex. 1009, 1:12-16; 3:4.)

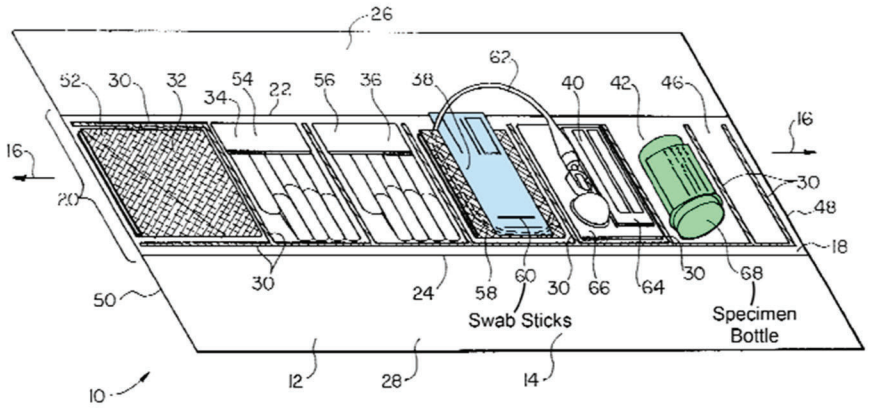


FIG. 1

395. In view of Salvadori, a POSA would have been motivated to include swabsticks—a common device used with a catheterized patient—in the catheterization kit of Solazzo to allow a practitioner to cleanse the patient's genitals prior to insertion of the catheter. Trays with swabs for cleaning a patient were common in the prior art. For example, Serany teaches "forceps" and "balls 34 of cleansing material" that provide the exact same function as swabsticks, i.e.,

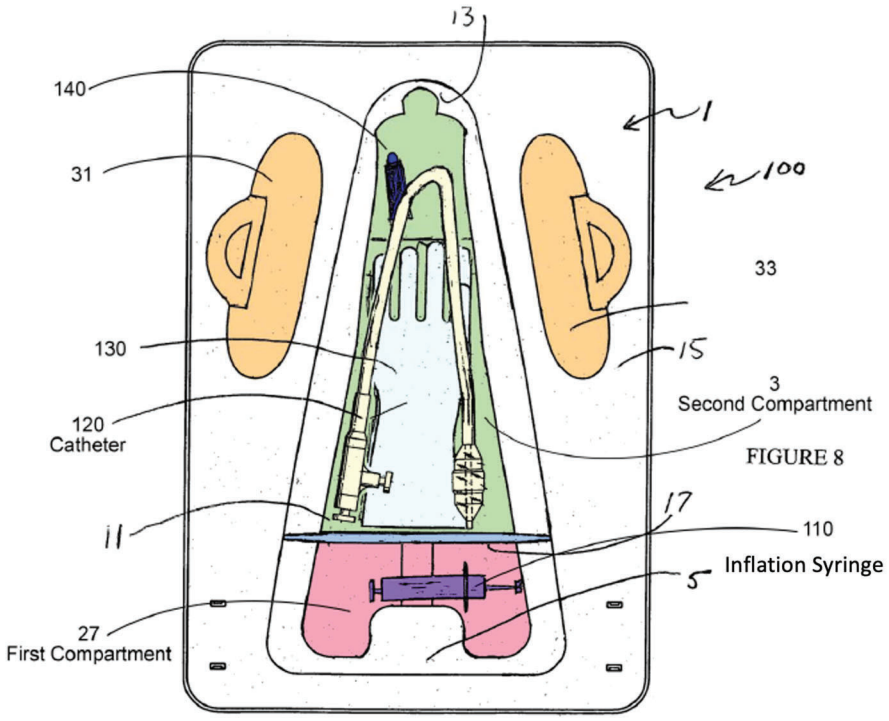
they are used to cleanse the patient prior to insertion of the catheter. (Ex. 1009, 2:57-65.) This is thus a simple substitution of one known element (forceps and an absorbent material such as cotton) for another swabsticks (i.e., an absorbent material with a handle) to yield predictable results (making the swabsticks easier to grasp because of the handle as compared with manipulating forceps to pick up cotton).

396. Furthermore, the inclusion of a swabsticks in the catheterization kit of Solazzo involves the use of a known technique (provision of swab sticks) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (providing swab sticks to allow the practitioner to clean the patient before insertion of the Foley catheter).

397. The Board previously found it would have been obvious to include swabsticks in the kit of Solazzo. (Ex. 1015 at 26-27.)

398. **Storing swabsticks in the third compartment.** Solazzo discloses four compartments: first compartment 27, second compartment 3, and compartments 31 and 33. (Ex. 1005.Figs.1,8.2:52:3:25.) Either of lubricating wells 31 and 33 is a "third compartment" as they meet the structural requirements of a compartment as defined recessed area of a tray that can accommodate components, including the position of the catheter that is passed into the compartments to lubricate it. (Ex. 1005 at 4:21-25;Figs.1,3,8.) Additionally, Solazzo use the term "wells" and

compartments interchangeably as Solazzo states both that divider wall 17 creates "two separate compartments" and an "irrigation well" and "drainage well." (Ex. 1005 at 4:15-16; 5:12-16.)



399. It would have been obvious for a POSA to try using compartment 31 or 33 to contain swabsticks given the finite number of identified, predictable solutions for storing the swabsticks (i.e., in compartment, 3, 27, or 31/33) with a reasonable expectation of success.

400. There are only four options for storing the swabsticks (compartments 3, 27, 31, or 31 and two of them (31 or 33) could be the claimed "third compartment." A POSA would have had ample reason to avail himself of the obvious option of storing swabsticks in the third compartment.

401. First, it was known to store equipment (including swabsticks) in a separate designated location away from other equipment. Solazzo disclose storing equipment such as the Foley catheter 120, a tube of lubricant 140, and gloves in compartment 3. (Ex. 1005 at Figure 8.) In Salvadori, the swabsticks are stored in a separate location (in pocket 38) that is different from where the "lubricating gel 64" (in pocket 40) and "gloves 54, 56" (in pockets 34 and 36). (Ex. 1013 at 3:2-8, Fig.1.)

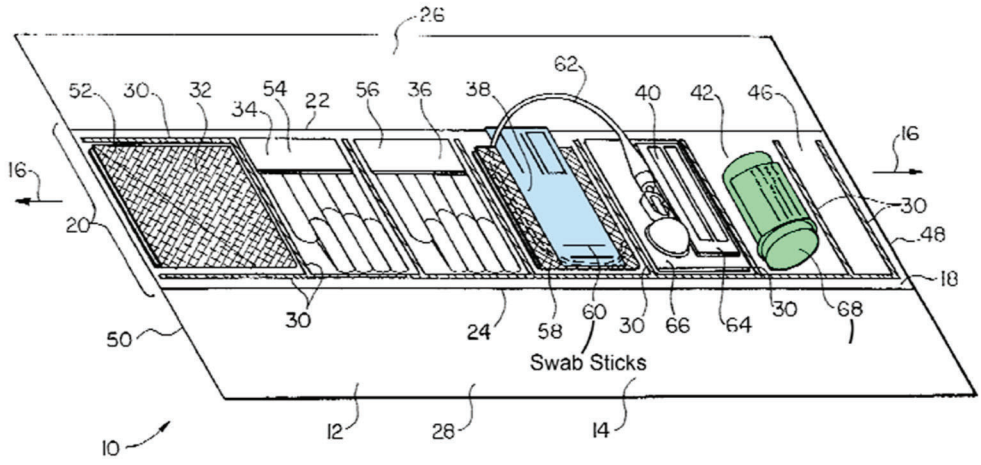


FIG. 1

402. Similarly, Serany stores forceps 36 and balls 34 in a separate location (which provide the same function as swabsticks) in a separate compartment of the tray away from other equipment. (Ex. 1009 at 2:57-72, Fig.6)

403. This teaching is further consistent with Serany, which stores forceps 36 and balls 34 in a separate (which provide the same function as swabsticks) in a

separate compartment of the tray away from other equipment, including the inflation syringe 44. (Ex. 1009, 2:57-72, Fig. 6)

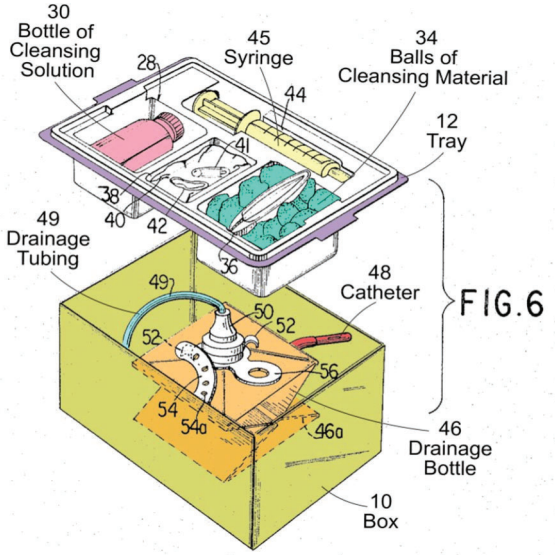


FIG.6

404. In view of Salvadori and Serany, a POSA would have been motivated to store the swabsticks in a different location in the tray from the lubricant and gloves (provided in compartment 3) as well as away in a different location in the tray than compartment 27 that stores at least the inflation syringe. A POSA would also have been motivated to store the swabsticks in a different location in the tray than compartment because it stores the Foley catheter, which is a medical device that is inserted into the human body, and storing equipment in separate compartment would avoid the risk of damaging the Foley catheter.

405. As noted above, an obvious choice for storing the swabsticks is therefore compartment 31 or 33, which Figure 8 shows are not used for storing any equipment, making them available for storing the swabsticks. (Ex. 1005 at Fig. 8.)

406. There would have been additional motivation in view of Serany to select compartment 31 or 33 to store the swabsticks to arrange items "in logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:23-35.) Specifically, compartments 31 and 33 are positioned near the front of the tray which is "tapered" to be placed between the legs such the compartments such that they are close to the patient's genitals. (Ex. 1005 at 1:7-13, 2:34-47, Figs.1-5, 8.)

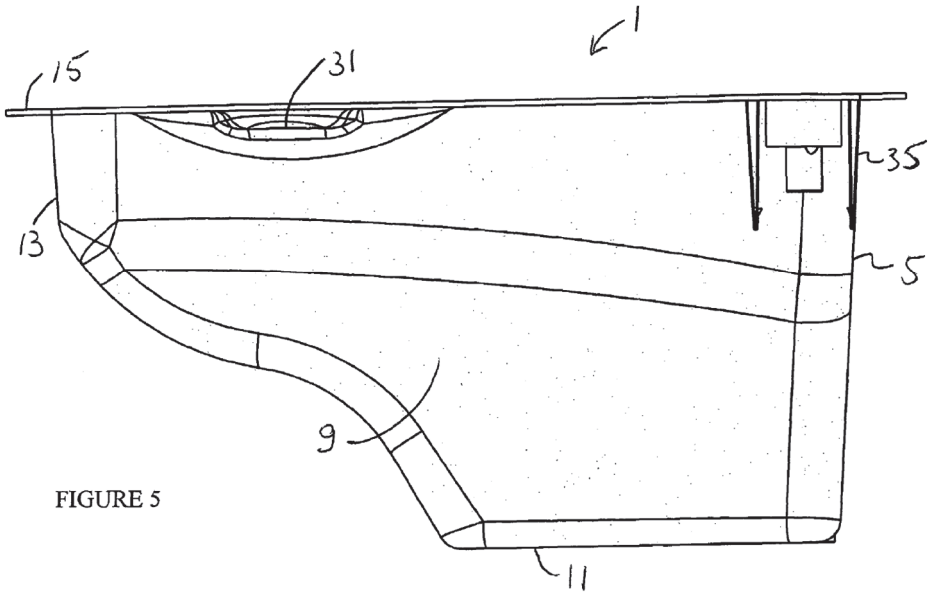


FIGURE 5

407. Compartments 31 or 33 are thus a logical place to store swabsticks given they are used to clean the patient's genitals. Additionally, I understand from Dr. Yun that the patient's genitals needed to be cleaned before the catheter is inserted, and thus the swabsticks may be used to clean the patient prior to lubricating the catheter and certainly need to be used before inserting the catheter and inflating the balloon of the catheter. (Ex. 1003 ¶¶ 46-47.) Because the swabsticks are used

early in the procedure, storing them at the top of the tray positions them in their order of use, which was obvious in view of Serany' teaching of arranging "**all the components** in logical step-by-step order to facilitate the nurse's or physician's task." (Ex. 1009 at 1:15-35 (emphasis added). This further means that storing the swabsticks in one of the lubrication wells does not interfere with the lubrication function of the wells because the swabsticks can be used to clean the patient before the catheter is lubricated. In any event, there are multiple wells for "right handed and left handed users" and the swabsticks could simply be moved to a different well if for some reason the clinician preferred to lubricate the catheter before cleaning the patient's genitals.

408. A POSA would have understood that swabsticks, including Salvadori's swabsticks, would have fit within one of the lubrication wells. Although Salvadori's does not provide a size for the swabsticks, a POSA would have understood that they are not particularly large. Indeed, they are shown in Figure 1 as fitting within a pocket 38 of Salvadori's rolled package. (Ex. 1013 at Abstract, Fig. 1 ("Components are placed in the pockets in order of use, and the wrapping is rolled up, beginning with the pocket containing the last used component.)

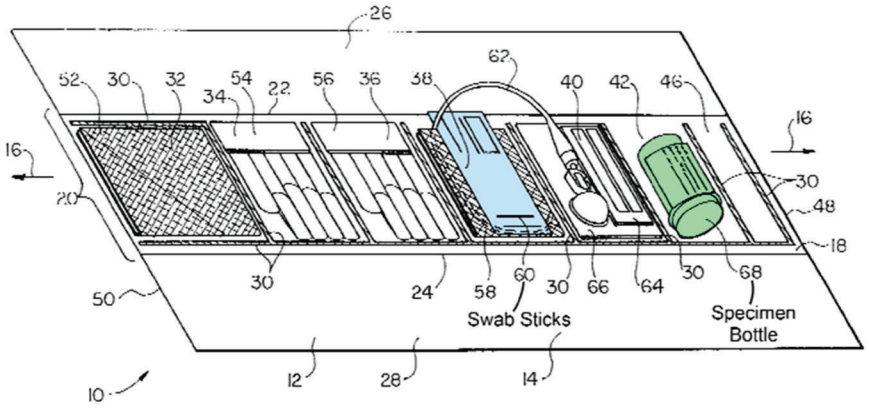
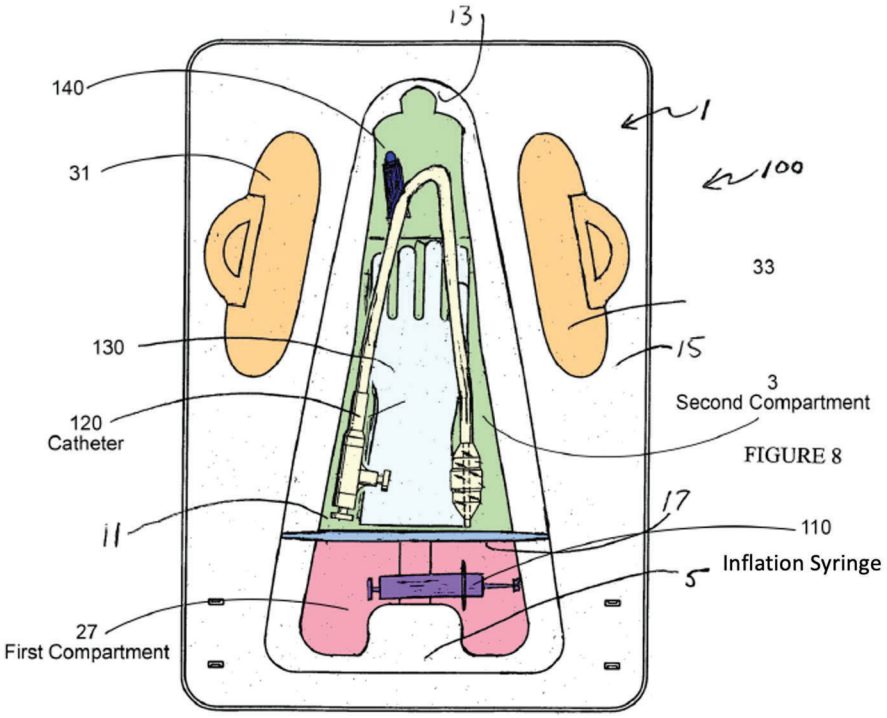


FIG. 1

409. Practically swabsticks also do not need to be particularly large to perform their intended function of cleaning the patient's genitals. They simply need an absorbent tip that can be less than an inch in length and a handle of a few inches, meaning that swabsticks would typically be under five inches long (e.g., around four inches long). Additionally, the handle of a swabstick would generally have a diameter much smaller than a Foley catheter such that multiple swabsticks could fit in a compartment that is designed to hold a catheter. Indeed, as discussed above, the Medline brochure from 2008 discloses a Foley catheter kit with swabsticks and the dimensions of those PVP swabsticks are consistent with the dimensions I mentioned above.

410. The size of Solazzo's lubricating wells are not provided, but a POSA would generally understand them to likely be at least around five to six inches given that it up to five inches of the catheter sometimes needs to be lubricated and they would be made somewhat larger to provide some margin of error. (Ex. 1003 ¶ 135.)

While I understand that patent drawings are not considered to scale unless indicated, such a length is at least consistent with the drawings, which for example, depicts the lubricating wells as being a bit longer than the inflation syringe (typically around six inches).



(Ex. 1008 at Fig. 8.)

411. Thus, swabsticks (which would be less than five inches and have a diameter smaller than a typical Foley catheter) would fit within a lubricating well that would likely be designed to around five to six inches, as discussed above. Additionally, it would have been trivial to modify the compartment (e.g., make it a bit longer or wider) to accommodate swabsticks using know manufacturing methods and a POSA would have been motivation do so because is a fundamental principle

of packaging to size compartments to fit the components within. Again, the size needed to accommodate swabsticks is similar to the size needed to accommodate a Foley catheter. Moreover, the lubricating wells are provided on flange 15, which "acts in part so that a patient may have flange 15 rest on front upper portions of the patient's legs when in a seated position." (Ex. 1005 at 3:66-4:3; Figs. 1, 3, 5.) A POSA would ideally be several inches wide near the front of the tray to provide stability—leaving plenty of room for compartments 31 or 33 that accommodate swabsticks.

412. Accordingly, Solazzo in view of Salvadori and Serany discloses this claim element. Solazzo in view of Serany, Disston, Imai, and Salvadori thus renders claim 13 obvious.

2. Claim 16

413. Solazzo discloses "*a boundary surface defines the lubricating jelly application chambe*r." Specifically, a POSA would understand that flange 15 of Solazzo is a boundary surface of the tray because it defines the boundaries of the tray and forms the outer edge of the tray. (Ex. 1005 at 3:52-4:3, Figs. 1-3.)

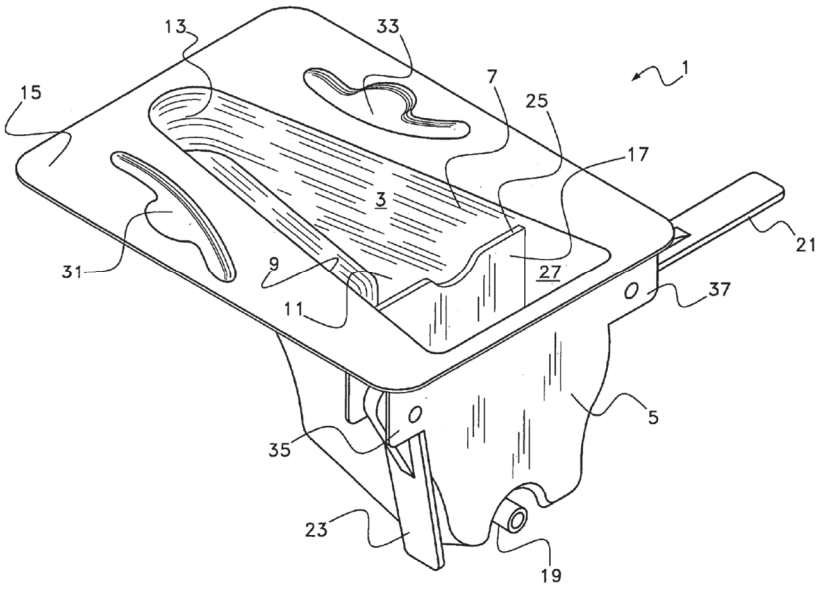
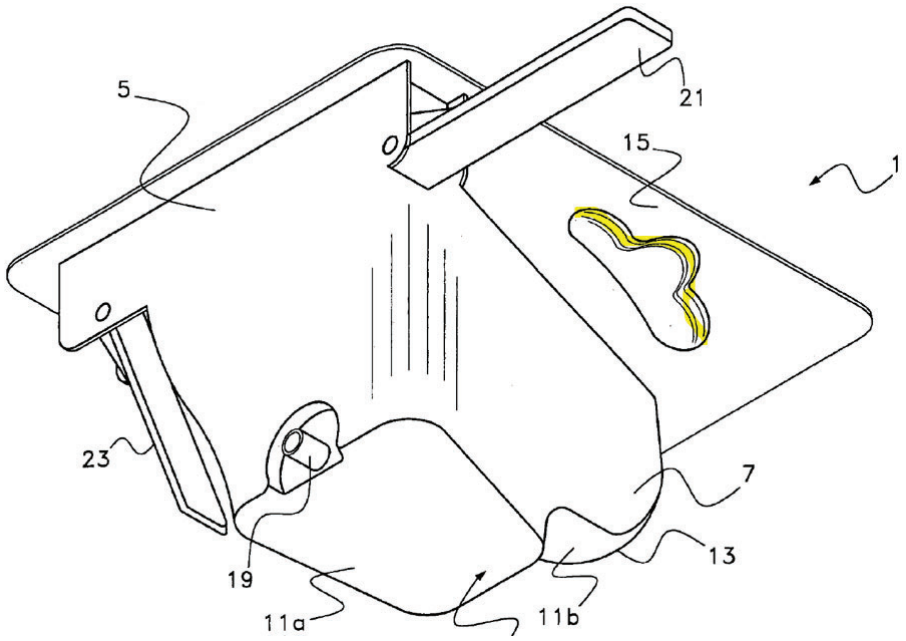


Fig. 1

414. As shown in Figure 1 above, lubricating wells 31 and 33 are provided on flange 15, which is a boundary surface of the tray. Accordingly, the bottom surface of these compartments, which are part of the flange, form a boundary surface of the tray. This is further illustrated in Figure 2 of Solazzo below, which shows the underside of the tray (with the lubricating well highlighted in yellow), and thus confirms that a boundary surface of the tray defines the lubricating jelly application chamber:



415. Accordingly, Solazzo in view of Salvadori and Serany discloses this claim element. Solazzo in view of Serany, Disston, Imai, and Salvadori thus renders claim 16 obvious.

XI. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

416. To the extent Medline contends that it can tie its secondary considerations evidence to a single layer tray feature, I disagree. As described in Section V, the claims of the ’219 patent are very similar to the cancelled claims of related Medline patents. None of the additional claim limitations added by the ’219 patent such as a “third compartment” add anything with respect to secondary considerations of non-obviousness.

417. I understand the Board had concluded previously Medline cannot establish a presumption of nexus because the claim features of a single layer tray and syringes arranged in their order of use (which Medline had identified as critical features) were in the prior art. (Ex. 1014 at 61-63.) I have described several prior art single layer urinary catheter kits in my report, including Solazzo, Rauschenberger, Disston, and Numata, as well as references that teach items arranged in their order of use, such as Solazzo, Serany Disston, Salvadori, and Rauschenberger. For example, the PTAB stated: "Patent Owner's argument is unpersuasive. There is no dispute that Solazzo's tray 1 is a single layer tray, and the Federal Circuit expressly concluded that Solazzo alone or in combination with Serany suggests arranging syringes based on their order of use." (Ex. 1014 at 62.)

418. Additionally, I understand the Board reviewed Medline's evidence for each of the secondary considerations factors and found it lacking. (Ex. 1016 at 20-39; Ex. 1014 at 54-76; Ex. 1015 at 40-57.) With respect to long-felt need, the PTAB found that Medline could not show that the claimed invention contributed to a reduction in CAUTI: "Petitioner persuasively demonstrates that CAUTI rates declined steadily before single level trays gained market share and thus decreased for reasons unrelated to the claimed tray." (Ex. 1014 at 63-65.) The Board also found that the copying factor did not weigh strongly in favor of non-obviousness. (Ex. 1014 at 65-69.) The Board recognized there were some commonalities between the

trays (i.e., both single layer), but noted that the layout of the SureStep tray was more similar to the Rauschenberger patent from the 1970s than the ERASE CAUTI tray. (Ex. 1014 at 65-69.)

419. As for failure of others, the PTAB concluded that Bard relying on a design contest in coming up with the Accused SureStep tray was not indicative of any failure on the part of Bard. (Ex. 1014 at 69-70.) Finally, the Board found that other factors, including brand loyalty, GPOs, price, and quality (and not Medline's claimed inventions) drove the commercial success of the Accused SureStep trays and Medline's own Foley catheter tray products. (Ex. 1014 at 70-76.)

420. In sum, consistent with the Board's previous findings, it my opinion that secondary considerations does not weigh in favor of non-obviousness. To the extent that such evidence has any bearing on obviousness, it would not be enough to outweigh the strong *prima facie* case of obviousness.

XII. CONCLUSION

421. For at least the preceding reasons, it is my opinion that claims 1-7 and 9-16 of the '219 patent are unpatentable pursuant to 35 U.S.C. § 103.

422. This declaration is based on my present assessment of materials and information currently available to me. My investigation and assessment may continue, which may include reviewing documents and other information that may yet be made available to me. Accordingly, I expressly reserve the right to continue

my study in connection with this case and to expand or modify my opinions and conclusions as my study continues.

423. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the petition for *inter partes* review.

Executed on January 3, 2025



Karl R. Leinsing

Exhibit A



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kleinsing@comcast.net

Professional Summary

Medical device experience since 1992 and mechanical engineering experience since 1988. Areas of expertise include full life cycle medical device product development and consulting from conception through design, manufacturing, testing, qualification, validation, verification, qualification, packaging, labeling, clinical trials, FDA & EU regulatory approval, marketing, and sales training. Granted 41 patents, 7 awards, device published on cover of Life Magazine (May 2000), recognized as one of 100 notable people in the medical device industry by the Medical Device & Diagnostic Industry (MD&DI) in June 2008, recognized by Better Business Bureau and NH Magazine in 2013, and served as chairman of the Medical Device & Manufacturing Conference in 2014, and served on many boards.

Employment History

From: 2006 **ATech Designs, Inc.**
To: Present
Position: *President*

- Medical device product development and consulting since 1998 (formerly Innovative Engineering, Inc. in North Carolina)
- Developed cardiovascular, mitral valve repair (for 3 companies), surgical, intravenous, endoluminal, and percutaneous devices including market analysis.
- Consulting on bedside blood glucose level analyzer / cartridge, glucose sensors, peritoneal dialysis pumps, safety syringes, disinfecting caps, auto-injectors, pen injectors, urinary catheters, insulin pumps, subcutaneous ports & catheters, bed rails, e-cigarettes/pharmaceutical inhalers, bone anchors, bone plates/screws, staplers, device support arms, & walkers/rollators.
- Developed medical textiles, CPAP device for HDM, catheter dressing for H2L, trachea alarm for Innovations Unlimited, urinary incontinence device for a urologist, and stapler/suturing for SubQ It
- Invented and developed Programmable Electrode Array Knitter (6,158,250) to manufacture RF mesh for endometrial ablation device
- Litigation consulting and expert witness (patent & liability cases) in United States, Canada, EPO, USPTO, ITC, and Australia
- Visit www.atechdesigns.com for more information

From: 2005 **Mitralign, Inc.**
To: 2006
Position: *Director of Biomedical Engineering*

- Developed implants required for percutaneous mitral valve repair
- Invented & developed new tissue anchors within 2 months of hire
- Completed locker implant used to plicate the anchors & lock sutures



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From: 2002 **ONUX Medical, Inc.**
To: 2005
Position: *Manager of Design Engineering*

- Invented, developed, and tested a needlescopic Nitinol fixation device for abdominal aortic aneurysm (AAA) repair in 10 months (patent pending)
- Performed animal studies and trained surgeons on use of device
- Designed a disposable laparoscopic Q-ring fixation device below cost targets and performed market comparison study.
- Design history files were ISO compliant and most organized in the company

From: 1992 **IVAC/imed/Eli Lilly/ALARIS/Cardinal Health/CareFusion/BD**
To: 2002
Position: *Sr. Principal Design Engineer (Director Level Engineer)*

- Worked on development of medical drug infusion products including, but not limited to, disposable sets and components, syringe pump, pump systems, valves, and pump segments, insulin injection system for Eli Lilly, vial adapters, dialysis set components, catheters, and needle-free valves.
- Extensive knowledge of polymer selection, high volume production, IV therapy, chemical resistance, fracture mechanics, measurement equipment, design-of-experiments (DOE) & EtO/Gamma/E-beam sterilization, and packaging.
- Performed market analysis including focus studies.
- Researched and selected injection, compression, injection-compression, transfer, flashless, liquid injection molding (LIM), gum injection, vertical, and rotary molding methods by working closely with molding suppliers
- Designed plastic parts, ultrasonic welding fixtures and processes, decoupled molding processes, high speed leak and flow testing systems, UV adhesive and solvent joints, and automation
- Promoted five times - Product Eng. II to Sr. Principal Design Eng.
- Managed projects throughout product life cycle
- Sole inventor of the $300 million SmartSite® Needle-Free Valve that leads the sales of IV pumps and disposables (project identified as the most successful project in the history of the company)
- Granted many patents for the SmartSite® Needle-Free Valve
- Winner of 5 design awards - 1998 Medical Design Excellence Award (MDEA), 1999 NC Governors New Product Award, 2000 NSPE New Product Award, 2001 Prototype Design Award, and 2003 MDEA Gold Winner



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From: 1990 **Draper Corporation**
To: 1992
Position: *Mechanical Design Engineer*

- Designed textile loom & knitting machines
- Used knowledge of tribology, cams, gears, bearings, servo motors, electromagnetics, pneumatics, PLC's, PC oscilloscopes, and sensors
- Deflection and stress analysis using own finite element programs
- Electromagnetic analysis using MSC/XL-EMAS

From: 1988 **Harris Graphics Corporation**
To: 1990
Position: *Design Engineer* - Web offset printing press design

From: 1987 **Materials Lab, Inc.**
To: 1988
Position: *Analyst* - Analyzed and designed plasma arc cutters

From: 1986 **Walker Power, Inc.**
To: 1987
Position: *Mechanical Designer* - Designed textile wrap-spin machine

From: 1979 **KRL Electronics, Inc. (Bantry Components) / Solarmetrics, Inc.**
To: 1986
Position: *Technician* - Designed automated resistor equipment, inventory management, assembled and tested solar controls and air-wrap systems.

Publications

- 1995 - Thesis: Strength of Medical Thermoplastic Female Luers Exposed to Chemicals
- 2001 - Chemical Compatibility and the SmartSite® Needle-Free Valve
- 2013 - How a Medical Device Expert Witness Can Assist in a Case
- 2015 - A-Z Guide to Expert Witnessing ISBN: 9781892904454 (CV – pp.576 - 580)

Lectures

- 1998 - Lectured MD&M Seminar on “The Science of Successful Product Design”
- 2014 - Chairman of the Medical Device & Manufacturing Conference
- 2014 to 2016 – Webinar Speaker on Medical Device Product Development Process



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Granted US Patents (Foreign filings of same are not included)

Patent No.	Issue Date	Title
12,076,507	09/03/2024	Integrated Sealing and Securing Device for Vascular Catheters
11,826,049	11/28/2023	Devices For Deploying Tissue Fasteners
11,517,437	12/06/2022	Cardiac Treatment System
11,406,500	08/09/2022	Cardiac Treatment System and Method
11,141,552	10/12/2021	Systems For Providing Low-Noise Positive Airway Pressure
10,881,834	01/05/2021	Safety Catheter System and Method
10,695,046	06/30/2020	Tissue Anchor and Anchoring System
10,420,644	09/24/2019	Cardiac Treatment System and Method
10,405,981	09/10/2019	Cardiac Treatment System
10,064,723	09/04/2018	Cardiac Treatment System and Method
RE46,927	07/03/2018	Heart Band W/Fillable Chambers to Modify Heart Valve
9,844,437	12/19/2017	Cardiac Treatment System and Method
9,814,454	11/14/2017	Tissue Anchor and Anchoring System
9,750,907	09/05/2017	Portable CPAP and Method for Reducing Noise Therefrom
9,707,378	07/18/2017	Safety Catheter System and Method
9,421,102	08/23/2016	Cardiac Treatment System and Method
9,375,543	06/28/2016	Systems For Providing Low-Noise Positive Airway Pressure
9,370,425	06/21/2016	Cardiac Treatment System and Method
8,951,286	02/10/2015	Tissue Anchor and Anchoring System
8,951,285	02/10/2015	Tissue Anchor, Anchoring System & Methods of Using
D717,954	11/18/2014	Heart Treatment Device
8,740,850	06/03/2014	Safety Catheter System & Method
8,177,768	05/15/2012	Vial Adapter with Needle-Free Valve for Use with Vials
8,092,363	01/10/2012	Heart Band W/Fillable Chambers to Modify Heart Valve
8,029,472	10/04/2011	Safety Catheter System and Method
7,497,848	03/03/2009	Needleless Medical Connector W/Expandable Valve
7,306,199	12/11/2007	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
7,244,249	07/17/2007	Needle-Free Medical Connector with Expandable Valve Mechanism and Method of Fluid Flow Control
7,184,825	02/27/2007	Needless Medical Connector Having Antimicrobial Agent
7,125,396	10/24/2006	Safety Catheter System and Method
7,104,520	09/12/2006	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
6,971,630	12/06/2005	Needle Free Medical Connector with Expanded Valve Mechanism and Method Of Fluid Flow Control
6,875,205	04/05/2005	Vial Adapter with Needle-Free Valve for use with Vials
6,802,490	10/12/2004	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
6,706,022	03/16/2004	Needleless Connector Expandable Valve Mechanism
D468,016	12/31/2002	Medical Fluid Connector
6,158,250	12/12/2000	Flat-Bed Knitting Machine and Method of Knitting
6,142,446	11/07/2000	Medical Adapter Needleless Valve & Sharpened Cannula
5,839,715	11/24/1998	Medical Adapter Needleless Valve & Sharpened Cannula
5,676,346	10/14/1997	Needleless Connector Valve
5,549,577	08/27/1996	Needleless Connector



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Published Patent Applications (others pending)

Pub. No.	Pub. Date	Title
US 2002/0133124	Sep. 19, 2002	Needleless Medical Connector Having Antimicrobial Agent
US 2003/0098430	May 29, 2003	Needle free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2003/0153895	Aug. 14, 2003	Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes
US 2003/0199835	Oct. 23, 2003	Needleless Medical Connector w/Expandable Valve Mech.
US 2003/0209681	Nov. 13, 2003	Needle-Free Medical Connector with Expandable Valve Mechanism and Method of Fluid Flow Control
US 2004/0073237	Apr. 15, 2004	Surgical Fastener and Delivery System
US 2004/0127854	Jul. 1, 2004	Safety Catheter System and Method
Us 2005/0006614	Jan. 13, 2005	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2005/0148994	Jul. 7, 2005	Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes
US 2007/0007478	Jan. 11, 2007	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2007/0010857	Jan. 11, 2007	Tissue Anchor, Anchoring System & Methods of Using
US 2007/0100284	May 3, 2007	Safety Catheter System and Method
US 2007/0276437	Nov. 29, 2007	Lockers for Surgical Tensioning Members and Methods of Using the Same to Secure Surgical Tensioning Members
US 2009/0062596	Mar. 5, 2009	Heart Band w/Fillable Chambers to Modify Heart Valve Function
US 2009/0076547	Mar. 19, 2009	Tissue Anchor and Anchoring System
US 2011/0230810	Sep. 22, 2011	Implantable Anti-Adhesion Three Layer Patch
US 2011/0319827	Dec. 29, 2011	Safety Catheter System and Method
US 2012/0059457	Mar. 8, 2012	Minimally Invasive Surgical Instrument for Delivery of Cardiac Devices
US 2014/0107405	Apr. 17, 2014	Cardiac Treatment System and Method
US 2014/0107406	Apr. 17, 2014	Cardiac Treatment System and Method
US 2014/0107775	Apr. 17, 2014	Cardiac Treatment System
US 2014/0288500	Sep. 25, 2014	Safety Catheter System and Method
US 2014/0299130	Oct. 9, 2014	Portable Positive Airway Pressure Apparatus and Method for Attenuating the Noise Emitted Therefrom
US 2014/0299132	Oct. 9, 2014	Systems and Methods for Providing Positive Airway Pressure in a Tube-Like Structure
US 2014/0299406	Oct. 9, 2014	Systems and Methods for Providing Low-Noise Positive Airway Pressure
US 2015/0173740	Jun. 25, 2015	Tissue Anchor and Anchoring System
US 2016/0015919	Jan. 21, 2016	Systems and Methods for Providing Low-Noise Positive Airway Pressure
US 2016/0045693	Feb. 18, 2016	Portable Positive Pressure Apparatus and Method for the Attenuating the Noise Emitted Therefrom
US 2016/0262890	Sep. 15, 2016	Cardiac Treatment System and Method
US 2016/0331880	Nov. 17, 2016	Cardiac Treatment System
US 2016/0346085	Dec. 1, 2016	Cardiac Treatment System and Method
US 2017/0368315	Dec. 28, 2017	Safety Catheter System and Method
US 2018/0028171	Feb. 1, 2018	Tissue Anchor and Anchoring System



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US 2018/0368980	Dec. 27, 2018	Cardiac Treatment System and Method
US 2019/0247623	Aug. 15, 2019	Integrated Sealing and Securing Device for Vascular Catheters and Methods for Use of Same
US 2019/0343636	Nov. 14, 2019	Cardiac Treatment System
US 2019/0358038	Nov. 28, 2019	Cardiac Treatment System and Method
US 2020/0330088	Oct. 22, 2020	Tissue Anchor and Anchoring System
US 2022/0378579	Dec. 1, 2022	Cardiac Treatment System and Method
US 2023/0285020	Sep. 14, 2023	Devices For Deploying Tissue Fasteners

Education & Licensing

Year	College/University	Degree
1988	University of New Hampshire	B.S. in Mechanical Engineering
1992	NH: 11437	Professional Engineering License
1995	North Carolina A&T State University	M.S. in Mechanical Engineering

Litigation Experience - (Testimony by report, deposition, declaration, or trial - last 4 years)

Arthrex vs. Parcus and Anika - Case No. 2:22-CV-0019-JLB-NPM – Middle District of Florida – Patent Litigation regarding bone syndesmosis (Defense) – Patent and prior art review, testing, analysis, and report. (October 2023 to March 2024)

NJoy vs. Juul – Case No. 337-TA-1372 – Washington, DC – ITC Patent Litigation regarding vaporizer devices (Defense) – Patent and prior art review, claim construction declaration, depositions, invalidity reports, and trial testimony. (September 2023 to June 2024)

Novo Nordisk vs. Teva (Saxenda) – Case No. 21-cv-01782-CFC – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, reports, deposition. (January 2022 – September 2023)

Novo Nordisk vs. Dr. Reddy's Lab (Ozempic (Semaglutide)) & [Rio, Sun, Zydus, Alvogen, and Mylan] – MDL No. 22-MD-3038 (CFC) and Case No. 22-cv-294 & 1040 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, claim construction declaration. (December 2021 – March 2024)

Microvention vs. Balt – Case No. 8:20-cv-02400-JLS-KES – Central District of California Western Division – Trade secret case regarding catheters and embolization coils (Defense) – Review alleged trade secrets, analysis, report. (June 2022 – December 2023)

Mizuho Orthopedic vs. Allen Medical – Case No. 1:21-cv-10979-NMG – District of Massachusetts – Patent litigation regarding surgical bed (Defense) – Patent and prior art analysis, IPR declaration. (February 2022 – October 2022)



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DNA Genotek vs. Spectrum Solutions - Case No. 21-cv-0516-DMS-LL – Southern District of California - Sample Collection (Defense) – Patent & prior art review, IPR declaration, report, and depositions. (October 2021 – February 2024)

OsteoMed vs. Stryker & Stryker vs. OsteoMed – Case No. 1:20-cv-6821 – Northern District of Illinois Eastern Division – Patent litigation regarding bone plates (Defense & Plaintiff) – Patent and prior art analysis, IPR declaration, deposition. Contact: Scott McBride of McAndrews, Held, & Malloy (312) 775-8131. (May 2021 – Present)

DexCom vs. Abbott and Abbott vs. DexCom – Case No: 6:21-cv-690 in Western District of TX and C.A. No. 21-977 in District of Delaware – Patent litigation regarding glucose sensors (Defense & Plaintiff respectively) – Patent analysis, IPR declaration, attend EPO hearing (parallel Europe case), reports, depositions, and jury trial. (April 2021 – Present)

Altria & US Smokeless Tobacco Co. vs RJR and Modoral Brands – Case No: 1:20-cv-00472-NCT-JLW – Middle District of NC – Patent litigation regarding vaping devices (Defense) – Invalidity analysis, reports, IPR declaration, depositions, trial. (June 2020 – September 2022)

Novo Nordisk vs Sandoz – Case No: 20-747 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Analysis, report, and deposition. (June 2020 – March 2022)

Earth Animal Ventures, Inc. vs. Sage Fulfillment, LLC. – Case No: 3:20-CV-00444-VAB – District of Connecticut – Metered dispensing syringe w/CBD (Defense) – Testing, report, and deposition. (May 2021 to April 2023)

Anthony Canning vs Medtronic – Case No: CV2019-053458 – The Superior Court of the State of Arizona – Circular Surgical Stapler (Plaintiff) – Report. (November 2020 – April 2022)

Provost vs. Neuro-Rehab Associates, Inc., Elliott Hospital, and Medline Industries, Inc. – Case No: 217-2019-CV-601 – New Hampshire Superior Court – Medline Rollator Liability Case (Plaintiff) – Failure analysis, report, deposition. (July 2020 – November 2021)

Boehringer Ingelheim vs. Lupin Altantis Holdings – Case No: 18-12663 (BRM) (TJB) – District Court of New Jersey – Patent litigation regarding powder inhaler (Plaintiff) – Report and deposition. (January 2020 – October 2021)

Boston Scientific vs. Micro-Tech – Case No: 18-1869-CFC-CJB – District of Delaware – Patent litigation regarding endometrial ablation device (Plaintiff) – Review of patents & products, fracture analysis, reports, deposition. (January 2020 – January 2022)

Novartis vs. Regeneron – ITC No: 337-TA-1207 – Washington, DC – Patent litigation regarding pre-filled syringe (Plaintiff) – Patent review, declarations, Markman hearing. (August 2019 – Present)



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Baxter vs. BD – Case No: 1:17-cv-07576 USDC North IL Eastern Division – Patent litigation on Fluid Reconstitution Device (Plaintiff) – Review patents, declaration, report, & deposition. Contact: Denis Sullivan of Barclay Damon, LLP in Syracuse, NY (315) 425-2828. (July 2019 – December 2023)

Edwards vs. Lindel, MD - Case No: 17 CVS 1936 – Superior Court Division of Surry County, NC – Liability case on endometrial ablation device (Plaintiff) – Review of documents, medical records, deposition. (March 2017 – December 2023)

Hologic vs. Minerva & Minerva vs. Hologic – Case Nos: 15-1031-SLR / 18-217-JFB-SRF / 20-925-JFB-SRF – District of DE & CA - Patent litigation on endometrial ablation (Plaintiff & Defense) – Patents, reports, declaration, depositions, and jury trial. (April 2017 – April 2023)

Dr. Augé vs. Stryker & Howmedica – Case No: 1:14-CV-1089-KG-SMV – District of New Mexico (Santa Fe Division) – Contract case on bone anchors, guides, drills, & inserters (Defense) – Review products, patents, report, deposition, jury trial. (January 2017 – May 2022)

Covidien vs. Ethicon & Ethicon vs. Covidien – Case No: 1:11-cv-00871 & Case No: 1:16-cv-00253-SJD – Southern District of Ohio Western Div. & Case No: 1:16-cv-12556-LTS – District of MA – Patent litigation on RF & ultrasonic vessel sealing and cutting (Defense & Plaintiff) – Reports, depositions, & trial. (Dec. 2016 – March 2021)

Boston Scientific vs. Cook – Case No: 15-980-LPS-CJB – District of Delaware – Patent litigation case regarding surgical clip (Plaintiff) – Review patents, reports, depositions, and jury trial. (August 2016 – June 2023)

Medline vs. CR Bard – Case No. 1:14-CV-3618 / 1:16-cv-3529 / 1:17-cv-7216 – Northern District of Illinois Eastern Div. – Catheter packaging and trays (Defense) – Claim construction declarations, depositions, testified at two Markman hearings. (January 2016 – Present)



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Declarations in Support or Response of IPR Petitions in Last 4 Years

Decl. Date	Petition #	Patent(s)	Parties / Type Device
10/22/2020	2020-01317 2020-01318	9.220,631	Novartis vs. Regeneron / Pre-Filled Syringe
3/12/2021	2021-00650 2021-00652	10,143,242 10,264,824	Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. R.J. Reynolds Vapor Company and Modoral Brands, Inc.
3/31/2021	2021-00744 2021-00745 2021-00746 2021-00747	10,299,517 10,485,269 10,492,541 10,588,357	Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. R.J. Reynolds Vapor Company and Modoral Brands, Inc.
07/28/2021	2021-00816	9,220,631	Novartis vs. Regeneron / Pre-Filled Syringe
04/23/2022	2022-00917 2022-00918	10,980,452	Dexcom vs. Abbott / Glucose Sensor
04/22/2022	2022-00919 2022-00920	10,888,481	Mizuho vs. Allen Medical & Hill-Rom / Surgical Table
11/16/2022	2022-01347	11,002,646	Genotek vs. Spectrum / Sample Collection
11/18/2022	2022-00487 2022-00488	9,078,713 10,993,751	Stryker vs OsteoMed / Bone Plates
9/14/2023	2023-01424	11,536,632	Genotek vs. Spectrum / Sample Collection
07/20/2024	2023-01409	11,202,591	Abbott vs Dexcom / Continuous Glucose Monitor
9/24/2024	2023-01424	11,536,632	Genotek vs. Spectrum / Sample Collection – Amended Claims

Note: Underlined party retained me to perform analysis and submit declaration.

Affiliations

ASME – American Society of Mechanical Engineers since 1988
National Society of Professional Engineers since 2000
ASM International – American Society of Metals International since 2020
UNH Mechanical Engineering Senior Project Sponsor & Leader - 2022
MDG – Medical Development Group since 2006
Inventors Workshop – Board of Directors since 2006
Eureka Medical – Medical Device Advisory Board since 2006
Big Brothers Big Sisters (BBBS) – Big Volunteer & Contributor – Since 2008
BBB – Better Business Bureau of New Hampshire since 2010
MassMedic – Massachusetts Medical Device Industry Council since 2011
Medical Device & Manufacturing (MD&M) Conferences – Chairman 2014
H2L Medical Technologies, LLC – Catheter Systems – Co-Founder – 2015 to 2018
Neighborhood Community Garbage Cleanup Committee Chairman – Since 2015



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UNH STEM (Tech Camp) – Mentor and Contributor – Science, Technology, Engineering, & Mathematics – Since 2016
All Electronic Toll (AET) - NH State Chairman – 2017
NH Bio-Made Industry and State Partnerships Board (ISPB) – Board of Directors - 2018