

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 IPR2025-00400

U.S. Patent No. 11,684,347

**DECLARATION OF KARL R. LEINSING, MSME, PE IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT 11,684,347**

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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. 11,684,347 (“the ’347 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 ’347 patent”, and the scientific and technical knowledge regarding the subject matter of the ’347 patent before and at the earliest effective U.S. filing date and/or priority date. I understand that Bard is challenging claims 1-11, 13-20 of the ’347 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 '347 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 '347 patent, (b) the prosecution file history of the '347 patent, (c) parent applications and patents of the '347 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 ’347 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 ’347 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 ’347 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 in and before 2009, and thus has expertise related to urethral catheterization procedures, which is relevant because the claimed inventions are directed to a kit that stores a Foley catheter (a common type of urethral catheter). Furthermore, much of the prior art discussed in this report is related to packaging for urethral catheters, and Dr. Yun's knowledge is therefore relevant. As noted above, I have 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 '347 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 '347 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 '347 PATENT

A. Description

31. The '347 patent was filed on December 19, 2020. It claims priority to a long series of patent applications, the earliest of which are is the June 30, 2009 filing of Patent Application No. 12/495,148. The '347 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 '347 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, 1:34–37.) The specification describes tray 100 shown in Figure 7 (annotated and colorized):

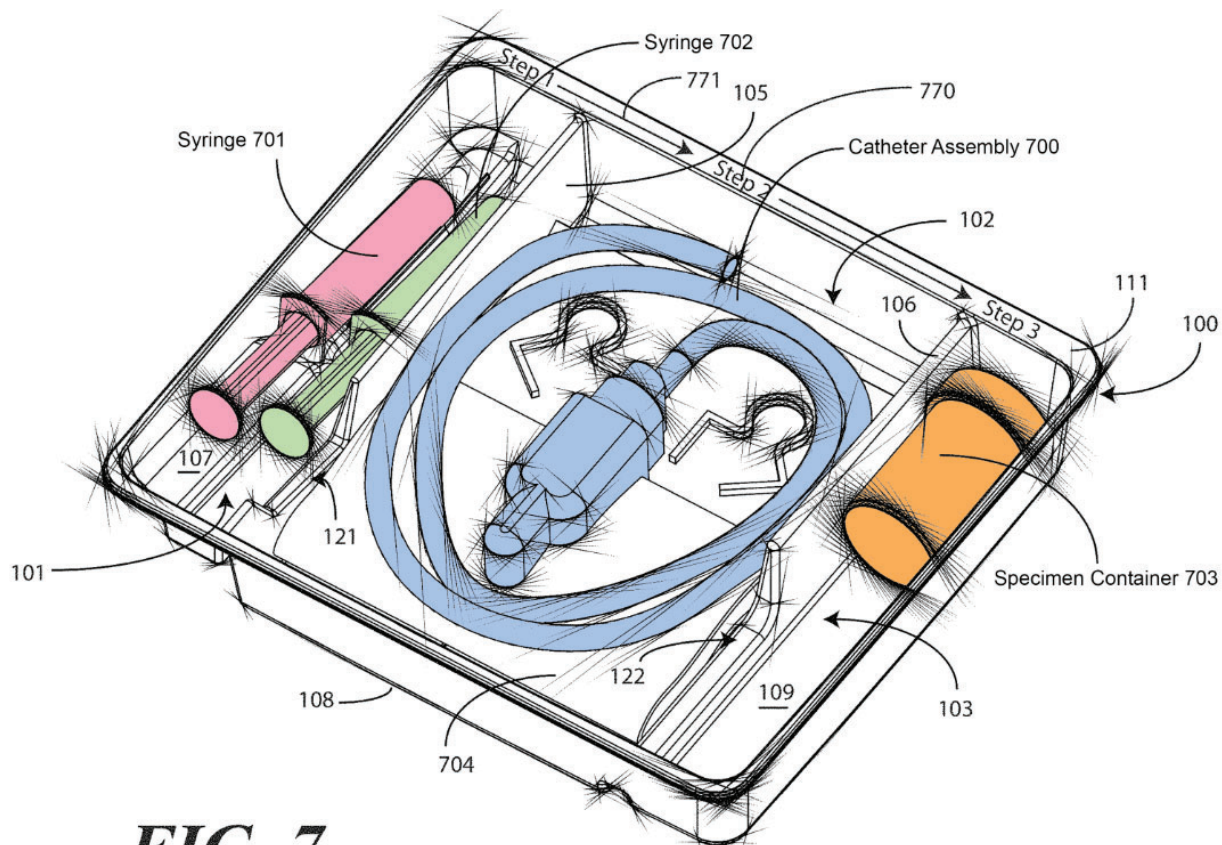


FIG. 7

(*Id.*, Fig. 7.)

33. As shown in Figure 7 above, the tray may include equipment such as syringes (provided in a first compartment 101) and a catheter assembly (provided in a second compartment 102).

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. Among the Challenged Claims, claims 1, 14, and 17 are independent.

For ease of reference, I have labeled the limitations of these claims as follows:

Claim 1	
1.p	A medical procedure kit, comprising:
1.a	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
1.b	a first syringe and a second syringe disposed within the first compartment; and
1.c	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
1.d	wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water; and

1.e	wherein the first compartment and the second compartment are adjacent and separated by a barrier.
Claim 14	
14.p	A medical procedure kit, comprising:
14.a	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
14.b	a first syringe and a second syringe disposed within the first compartment; and
14.c	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
14.d	wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water;
14.e	the first compartment and the second compartment are adjacent and separated by a barrier;
14.f	the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure; and
14.g	the first compartment supports the first syringe and the second syringe at different heights.
Claim 17	
17.p	A medical procedure kit, comprising:
17.a	a surface defining a single layer tray having a first compartment, adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag;

17.b	a first syringe and a second syringe disposed within the first compartment, the first syringe containing lubricating jelly and the second syringe containing water, wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure; and
17.c	the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment with the coiled tubing positioned between the Foley catheter and the fluid drain bag.

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 ’347 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 ’347 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 ’347 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 22 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.” (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 ’347 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. 1022) 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. (*Id.* 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).

(IPR2019-00208, Paper 57 (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.)

C. Comparison of '347 Patent Claims to Cancelled Claims of Related Patents

50. Below, I compare the claims challenged in Grounds 1 and 2 (i.e., the Grounds based on Solazzo) as compared to claims that have previously been invalidated in IPR decisions based on Solazzo.

1. Claim 1

51. Invalidated claim 47 of the '088 patent includes nearly every limitation of claim 1 of the '347 patent:

	'347 Patent		'088 Patent
1	A medical procedure kit, comprising:	45	A medical procedure kit, comprising:
1[a]	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;	45[a]	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
1[b]	a first syringe and a second syringe disposed within the first compartment; and	45[b]	a first syringe and a second syringe disposed within the first compartment;
1[c]	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;	45[c]	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
		45[d]	at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and
1[d]	wherein one of the first syringe or the second syringe contains	45[e]	an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.

	lubricating jelly and another of the first syringe or the second syringe contains water; and	47	46. The medical procedure kit of claim 45, wherein one of the first syringe or the second syringe contains lubricating jelly.
1[e]	<i>wherein the first compartment and the second compartment are adjacent and separated by a barrier.</i>		47. The medical procedure kit of claim 46, wherein another of the first syringe or the second syringe contains water.

(Ex. 1001 at claim 1; Ex. 1015.)

52. The only minor difference between invalidated claim 47 and claim 1 of the '347 patent is claim 1[e]—requiring “the first compartment and the second compartment are adjacent and separated by a barrier.” But the Board separately found that Solazzo discloses first and second compartments “separated by a barrier” in invalidating claims 61 and 77 of the '088 patent. (Ex. 1015 at 29-36.) While these claims did not expressly recite that such compartments are “adjacent,” two compartments that are separated by a barrier are necessarily adjacent. Indeed, the first compartment (compartment 27) and second compartment (compartment 3) of Solazzo, which are separated by a barrier (divider wall 27), are indisputably adjacent. (Ex. 1005, Fig. 1.)

2. Claim 2

53. Claim 2 recites: “The medical procedure kit of claim 1, further comprising an outer packaging disposed about the single layer tray.” This limitation is found in claim 45[e] of the '088 patent, as shown above.

3. Claim 5

54. Claim 5 recites: “The medical procedure kit of claim 1, wherein the water is sterile.” This limitation is found in invalidated claims 48, 64, and 80 of the ’088 patent: “wherein the water is sterile.” (Ex. 1015 at 22.)

4. Claim 6

55. Claim 6 recites: “The medical procedure kit of claim 5, further comprising a specimen jar disposed within the single layer tray.” This limitation is found in invalidated claims 49, 65, and 81 of the ’088 patent: “a specimen jar disposed within the single layer tray.” (Ex. 1015 at 23.)

5. Claim 7

56. Claim 7 recites: “The medical procedure kit of claim 1, wherein the first compartment is bounded by a first base member and the second compartment is bounded by a second base member.” This limitation is found in invalidated claim 7 of the ’596 patent: “ a first compartment bounded by a first compartment base member and ... a second compartment bounded, at least in part, by a second compartment base member.” (Ex. 1016 at 15-16.)

6. Claim 8

57. Claim 8 recites: “wherein a portion of the first base member and another portion of the second base member are substantially coplanar.” As discussed at claim 7, the Board previously found that Solazzo disclosed compartment base

members. Such base members are “*substantially coplanar*” as discussed at Ground 1, claim 8.

7. Claim 10

58. Claim 10 recites: “The medical procedure kit of claim 1, further comprising: “an outer packaging disposed about the single layer tray; a Foley catheter securement device disposed within the single layer tray; and one or more swabsticks disposed within the single layer tray.” These limitations are found in invalidated claims of the ’088 patent. Specifically, invalidated claim 45[e] of recites “an outer packaging disposed about [] the single layer tray.” (Ex. 1015 at 15-16.) Invalidated claims 55, 71, 87 recite “a Foley catheter securement device disposed within the single layer tray.” (Ex. 1015 at 28.) Invalidated claims 54, 70, and 86 recite: “one or more swabsticks disposed within the single layer tray.” (Ex. 1015 at 26-27.)

8. Claim 11

59. Claim 11 recites: “The medical procedure kit of claim 10, further comprising: an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.” These limitations are found in invalidated claims of the ’088 patent. Specifically, invalidated claims 56, 72, 88 of the ’088 patent recite: “an underbuttocks drape disposed within the outer

packaging.” (Ex. 1015 at 28.) Invalidated claims 60, 76, 92 of the ’088 patent recite: “a fenestrated drape disposed within the outer packaging.” (Ex. 1015 at 28.)

9. Claim 13

60. Claim 13 recites: “The medical procedure kit of claim 1, further comprising: a Foley catheter securement device; one or more swabsticks; a specimen jar; and an outer packaging disposed about the single layer tray.” These limitations are found in invalidated claims 45, 49, 54, 55, 65, 70, 81, 86, and 87 of the ’088 patent, as detailed above.

10. Claim 14

61. Claim 14 recites:

14. A medical procedure kit, comprising:

[a] a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;

[b] a first syringe and a second syringe disposed within the first compartment; and

[c] the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;

[e] wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water;

[f] the first compartment and the second compartment are adjacent and separated by a barrier;

[g] the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure; and

[h] the first compartment supports the first syringe and the second syringe at different heights.

62. Invalidated claim 25 of the '088 patent includes most limitations of claim 14, including “the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure” (25[e]) and “the first compartment to support the first syringe and the second syringe at different heights” (25[g]). (Ex. 1014 at 25.) Invalidated claims 32 and 33 (dependent on 25) of the '088 patent adds that the medical assembly is a “Foley catheter [coupled to a fluid bag] disposed within the second compartment.” (Ex. 1015 at 43-45.) Invalidated claim 36 of the '088 patents recites “the tray comprising a single tray.” (Ex. 1015 at 47-49.) As with claim 1, claim 14 also recites “the first compartment and the second compartment are adjacent,” which is incontrovertibly taught by Solazzo.

11. Claim 15

63. Claim 15 recites: “The medical procedure kit of claim 14, further comprising: an outer packaging disposed about the single layer tray; a Foley catheter securement device disposed within the single layer tray; and one or more swabsticks disposed within the single layer tray.” These limitations are found in invalidated claims 45, 54, 55, 70, 86, and 87 of the '088 patent, as detailed above.

12. Claim 16

64. Claim 16 recites: “The medical procedure kit of claim 15, further comprising: an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.” These limitations are found in invalidated claims 56, 60, 72, 76, 88, and 92 of the ’088 patent, as detailed above.

13. Claim 17

65. Claim 17 recites:

17. A medical procedure kit, comprising:

[a] a surface defining a single layer tray having a first compartment, adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag;

[b] a first syringe and a second syringe disposed within the first compartment, the first syringe containing lubricating jelly and the second syringe containing water, wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure; and

[c] the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment with the coiled tubing positioned between the Foley catheter and the fluid drain bag.

66. Again, with the exception of “adjacent,” all limitations of claim 17[a] are found in invalidated claim 61 of the ’088 patent. Claim 17[b] is found in invalidated claim 25 of the ’088 patent. (Ex. 1014 at 35.) Claim 17[c] requires “coiled tubing positioned between the Foley catheter and the fluid drain bag.”

Serany and Disston disclose coiled tubing that connects a drainage bag and Foley catheter and is thus “positioned between the Foley catheter and the fluid drain bag.”

67. To the extent this claim requires coiled tubing being positioned in a specific manner within the tray, the PTAB has already found positioning a Foley catheter above the bag to have been obvious in invalidating claim 7 of the '596 Patent (“the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter.”) (Ex. 1016 at 15-16.) There, I understand that the Federal Circuit found on appeal:

[T]he limitation amounts to no more than rearranging simple items (a fluid receptacle and catheter) in a tray. Serany’s disclosure, coupled with common sense, would have provided a skilled artisan with ample motivation to place the fluid receptacle under the catheter; such an arrangement would conveniently place the items in the order they are used during the procedure.

C. R. Bard v. Medline Indus. Inc., 2021 WL 3574043, at *7 (Fed. Cir. 2021).

68. Similarly, I understand the Board also previously invalidated claim 14 of the related '400 patent in view of Solazzo and Serany, which required “the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube.” (Ex. 1023 at 26-27.)

14. Claim 18

69. Claim 18 recites: “The medical procedure kit of claim 17, further comprising: one or more swabsticks disposed within the single layer tray; a Foley catheter securement device disposed within the single layer tray; and a specimen jar disposed within the single layer tray. These limitations are found in invalidated claims 49, 54, 55, 65, 70, 81, 86, and 87 of the ’088 patent, as detailed above.

15. Claim 19

70. Claim 19: “The medical procedure kit of claim 18, further comprising one or more layers of wrap material enclosing the single layer tray within one or more folds of the one or more layers of wrap material and an outer packaging disposed about the one or more folds of the one or more layers of wrap material.” Invalidated claim 1 of the ’088 patent recites: “at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and an outer packaging disposed about both the tray and the at least one layer of wrap material.” (Ex. 1014 at 24.)

VII. PROSECUTION HISTORY

71. The ’347 patent was filed on December 19, 2019 as patent application no. 16/721,718 with three independent claims (1, 14, and 17) each directed to a medical procedure kit comprising a tray, two syringes disposed within a first compartment, and a Foley catheter in a second compartment. (Ex. 1004, 5-8.)

72. On July 14, 2020, Medline submitted an IDS that included the Board's initial Final Written Decisions ("Initial FWDs") in IPR2019-00035, IPR2019-00036, IPR2019-00109, IPR2019-00208, and IPR2019-00023. (Ex. 1004, 190-91.) The Board had found in its initial Final Written Decisions ("initial FWDs") with respect to the '088 and '596 patents that a combination of Solazzo and Serany did not disclose or render obvious any of the challenged claims, including 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.) As noted above, each independent claim of the '347 patent requires two syringes in a first compartment.

73. On June 29, 2022, the Examiner signed an IDS indicating his consideration of the Board's Initial FWDs. (Ex. 1004 at 237.)

74. On July 7, 2022, the Examiner rejected claims 1-6 and 9-18 under nonstatutory double patenting, including rejecting claims 1, 14, and 17 in view of claims 1, 4, 13, 45-47 and 61 of the '088 patent and in view of claims 1, 14, and 17 of the '596 patent. (Ex. 1004 at 214-35.) The Examiner thus recognized that the limitations of the pending claims and the claims of the '088 and '596 patents overlapped. (*Id.*) However, the Examiner issued no obviousness rejections under Section 103, including no rejections based on the combination of Solazzo and Serany. (*Id.*)

75. 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.)

76. On October 7, 2022, Medline filed a terminal disclaimer to overcome the double patenting rejection. (Ex. 1004 at 334-35.) Medline also made minor amendments to dependent claims 4 and 7. (Ex. 1004 at 343-344.)

77. Following the issuance of the Remand Decisions, on October 8, 2022, Medline submitted an IDS including several references. (Ex. 1004 at 353-358.) However, Medline did not submit the Remand Decisions, which had issued more than a week earlier.

78. On October 26, 2022, the Examiner allowed all pending claims. The Examiner addressed certain references—but not Solazzo—and found them lacking. (Ex. 1004 at 783-91.) According to the Examiner, the closest prior art (U.S. Patent No. 4,811,847 to Reif) discloses a catheter assembly, a tray, and one syringe, but “lacks a second syringe, and does not arrange the syringe and catheter in separate compartments.” (Ex. 1004 at 789.) Notably, the reason that Examiner gave for distinguishing Reif (the alleged “closest prior art”) was found to have been disclosed by Solazzo both by the Federal Circuit and the Board on remand. The Examiner

also distinguished Pilger and Rauschenberger as not disclosing multiple syringes. Solazzo, which was not discussed in the Notice of Allowance, includes multiple syringes (*Id.*) The Examiner also did not discuss Numata in the Notice of Allowance, which I understand was not submitted during the prosecution of the '347 patent.

79. On January 18, 2023, Medline filed a request for continued examination and submitted new IDSs on January 18, 2023 and February 1, 2023. (Ex. 1004 at 861-62.) Medline again did not submit the Remand Decisions. (*Id.*) The Examiner issued another Notice of Allowance on February 9, 2023 without explanation. (Ex. 1004 at 877.) On March 17, 2023, Medline again filed a request for continued examination and submitted new IDSs on March 17, 2023, March 22, 2023, and April 6, 2023. (Ex. 1004 at 900-05, 911-13, 916-18.) Once again, Medline did not submit the Remand Decisions in these IDSs. (*Id.*) The Examiner issued a third and final Notice of Allowance on April 11, 2023 without explanation. (Ex. 1004 at 920-21.) The '347 patent subsequently issued.

VIII. CLAIM CONSTRUCTION

80. I understand the Board construed “a surface defining a single layer tray having a first compartment separated by a barrier from a second compartment” as “requiring that the first and second compartments and the barrier separating them be part of the same surface” in a proceeding regarding a related Medline patent. (Ex.

1015 at 33.) I have thus applied this construction when considering a substantively identical claim limitation in claim 17[a].

81. For the remainder of the claim terms in the '347 patent, I have thus applied the plain and ordinary meaning of the remainder of those terms.

IX. PRIOR ART

82. The Foley catheter was originally designed by Dr. Frederic Foley in collaboration with Charles Russel Bard. This design was adopted by 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).)

83. 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.)

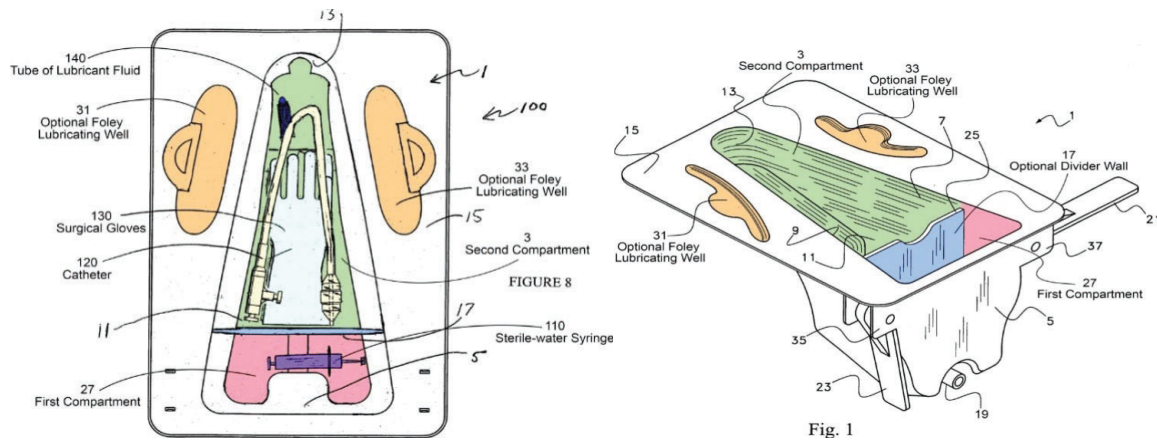
84. Medical device trays are packaged to allow trays to be shipped while holding the components inside the tray and may also hold the components within specific compartments of the tray. Bags, wraps, sealable lids, sleeves, and other forms of outer packaging were all common features of medical device 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.”

1. U.S. Patent No. 7,278,987 to Solazzo (“Solazzo”)

85. 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.)

86. I understand that, because Solazzo issued on October 9, 2007, more than one year prior to the earliest alleged priority date of the ’347 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

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



(Ex. 1005 at Figures 1 and 8.)

88. 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.)

89. 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.)

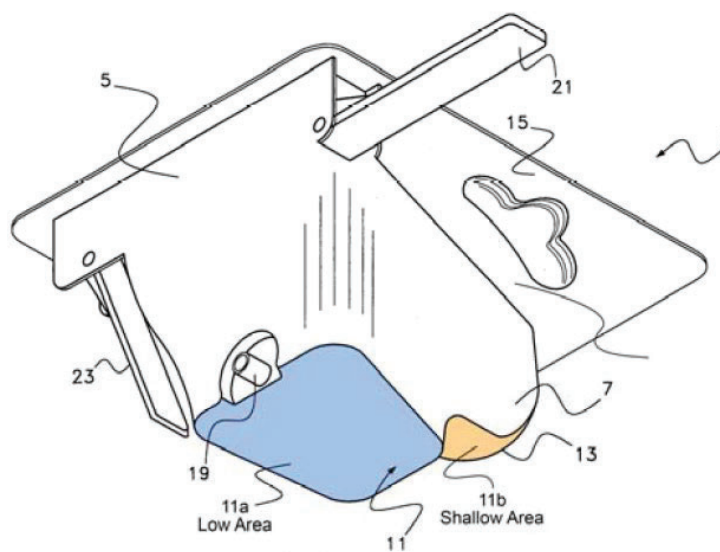


Fig. 2

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

90. 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.)

2. Japanese Patent Application Publication No. 2006-131284 to Numata (“Numata”)

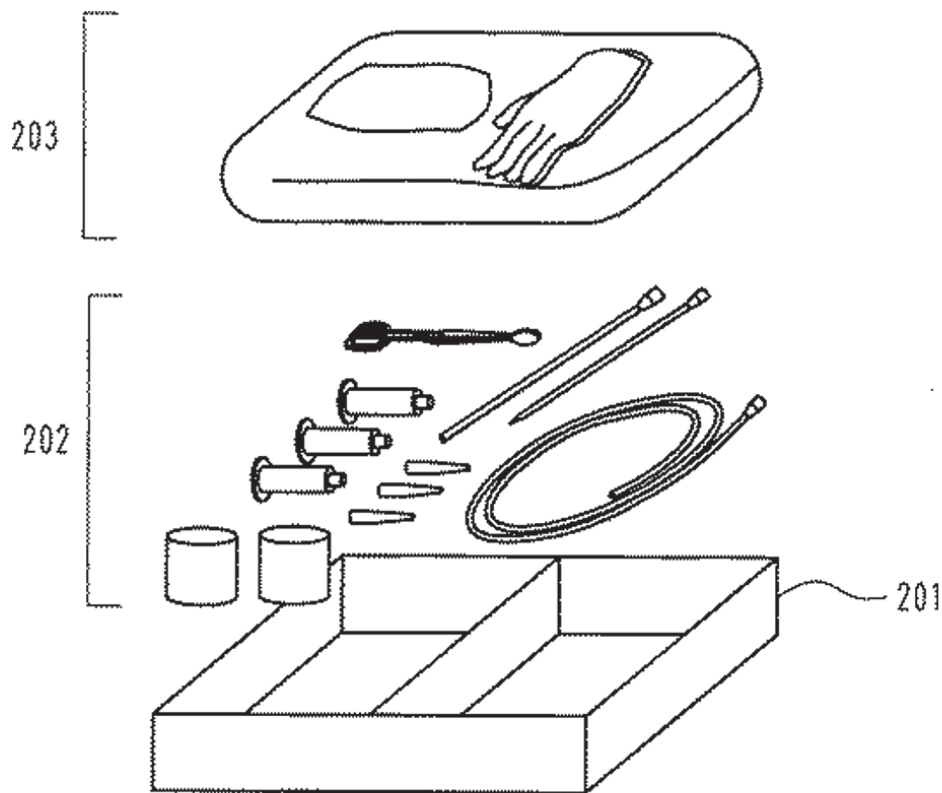
91. I understand that Japanese Patent Application Publication No. 2006-131284 to Shigeki Numata (“Numata”) was published on May 25, 2006. (Ex. 1006.) In this declaration, I rely on a certified translation of Numata. (Ex. 1007.)

92. I understand that because Numata was published on May 25, 2006, more than one year prior to the earliest alleged priority date of the ’347 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 ’347 patent.

93. 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.

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

(FIG. 4)



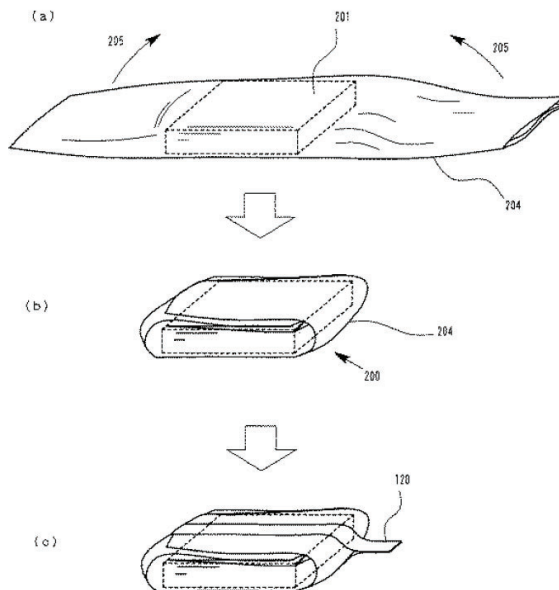
(Ex. 1007 at Fig. 4.)

95. 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.)

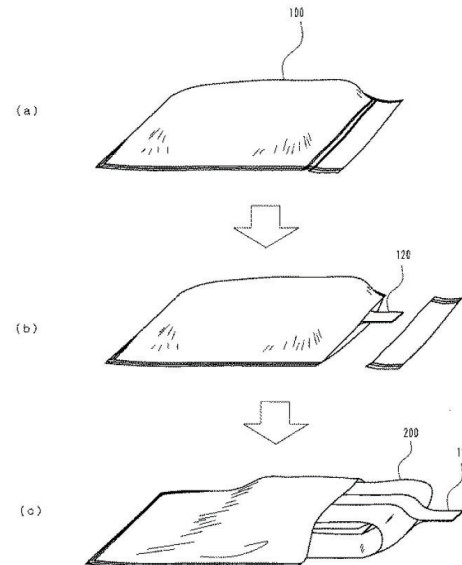
96. As with many of the prior art references discussed in my declaration, Numata utilizes the well-known solution of wrapping the tray in a wrap and then sealing the tray in a bag to keep the contents within sterile. Specifically, Numata’s

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.)

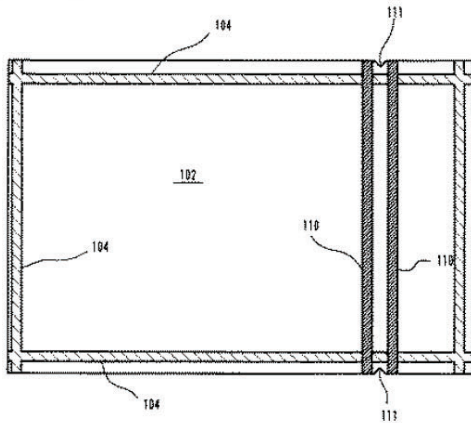
97. The packaging invention of Numata can be employed to store various types of medical equipment, and therefore is broadly directed to a “package body for storing medical instruments” for procedures “employing disposable medical instruments such as catheters.” (Ex. 1007 ¶0001.) The exemplary embodiment 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.)

As shown by numerous references cited throughout this declaration, Foley catheters were medical products sold sealed within packaging material in a sterilized state prior to 2009.

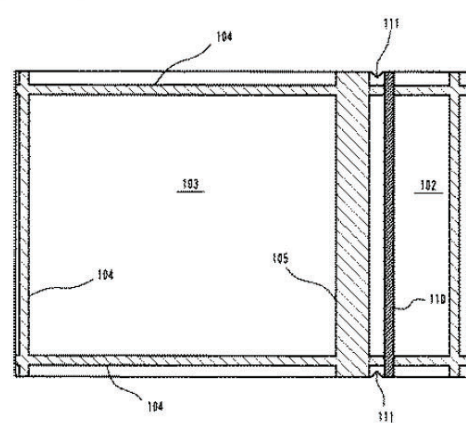
98. Numata's packaging solution allows for the removal of sterile medical instruments from inside a packaging bag "without directly touching the instruments with one's hands." (Ex. 1007 ¶ 0004.) Numata describes a problem that it seeks to solve as follows, noting that "physicians who have undergone thorough 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.)

99. 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)

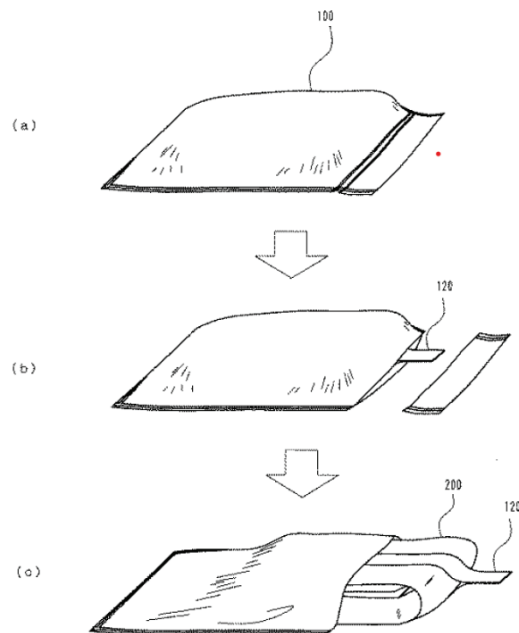


(FIG. 3)



100. 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,

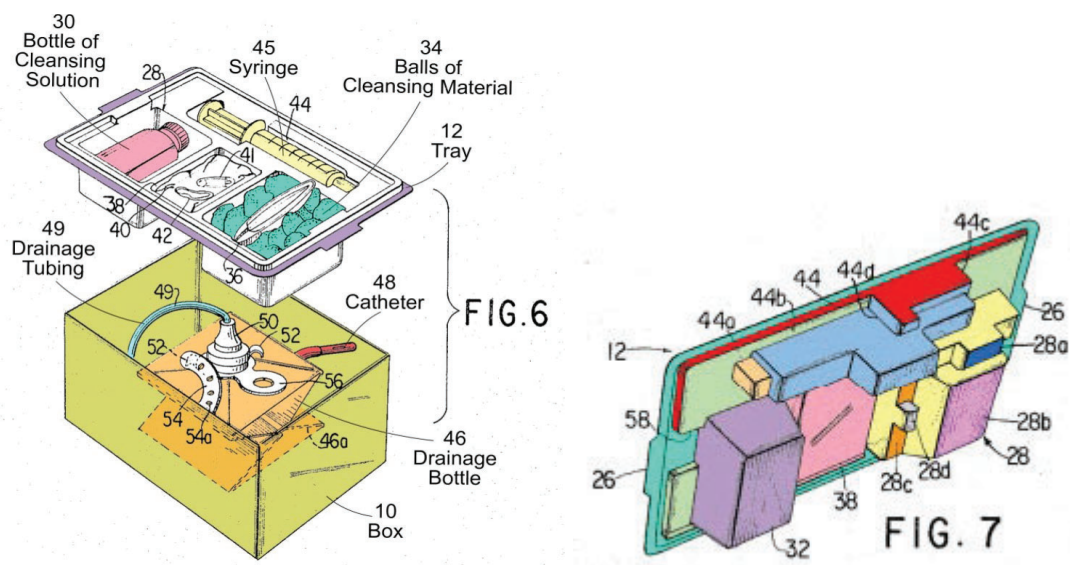
medical product 200 can be removed without the need to “directly touch[] the medical product 200 with one’s hands.” (Ex. 1007 ¶ 0036.)

3. U.S. Patent No. 3,329,261 to Serany (“Serany”)

101. 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.)

102. I understand that because Serany issued on July 4, 1967, more than one year prior to the earliest alleged priority date of the ’347 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.

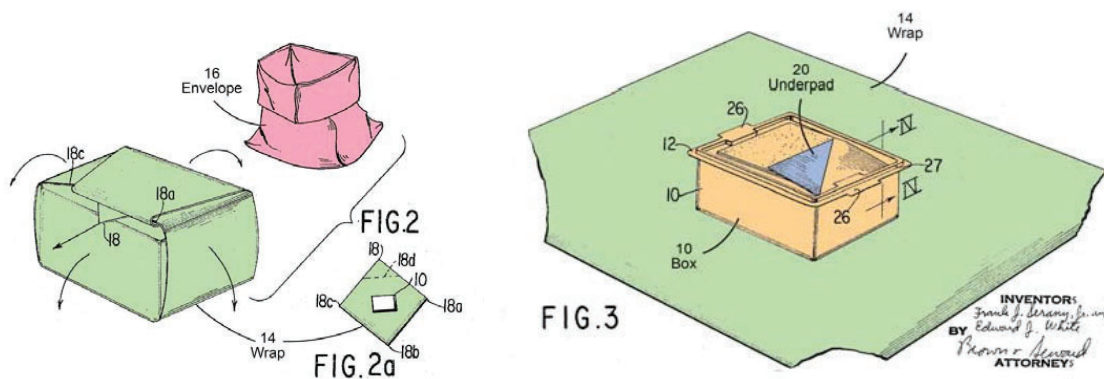
103. Serany discloses an all-in-one Foley catheter kit with common equipment used to perform a Foley catheterization. (Ex. 1009 at Fig. 6.) Specifically, the catheterization package of Serany includes a top tray and a bottom tray, as shown in Figure 6 (annotated with color and description):



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

104. 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.

105. 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.)



106. 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.)

107. 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.)

4. U.S. Patent No. 3,166,189 to Disston (“Disston”)

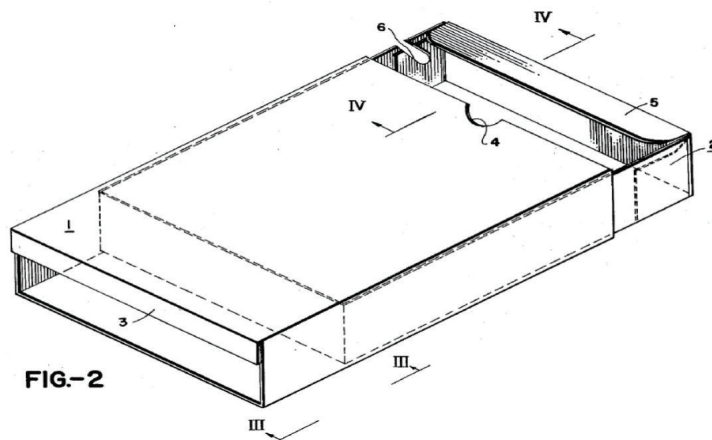
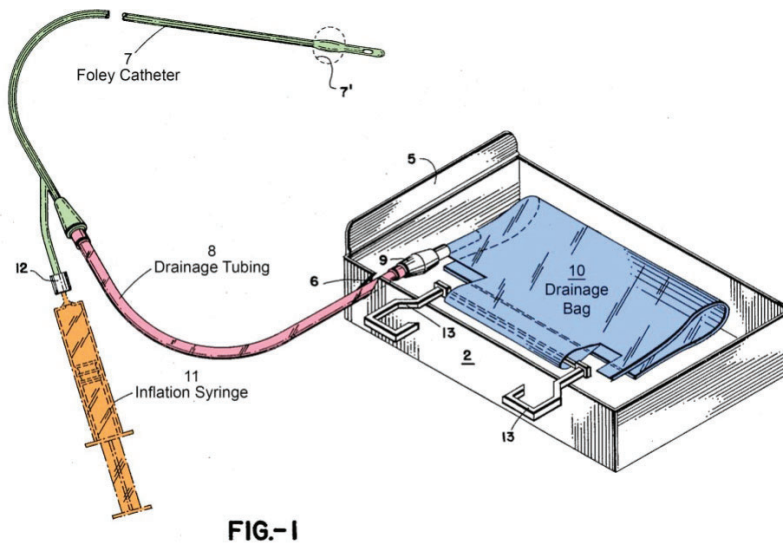
108. I understand that U.S. Patent No. 3,166,189 was issued to Hamilton S. Disston. As indicated on the face of the patent, it issued on January 19, 1965. (Ex. 1008.)

109. I understand that, because Disston issued on January 19, 1965, more than one year prior to the earliest alleged priority date of the ’347 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.

110. 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.)

111. 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.)



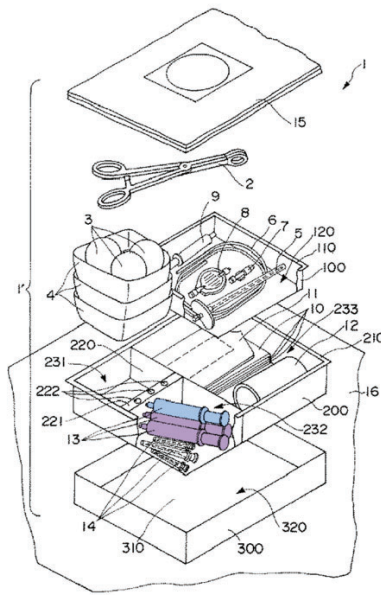
112. When opened, the tray of Disston presents contents including gloves, cleansing solution, protective pad or sheet, lubricant, sterile water packet, syringe, “and most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately.”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

5. Japanese Patent Application Publication No. 2007-229520 to Imai (“Imai”)

113. 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.

114. I understand that, because Imai published on September 13, 2007, more than one year prior to the earliest alleged priority date of the '347 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

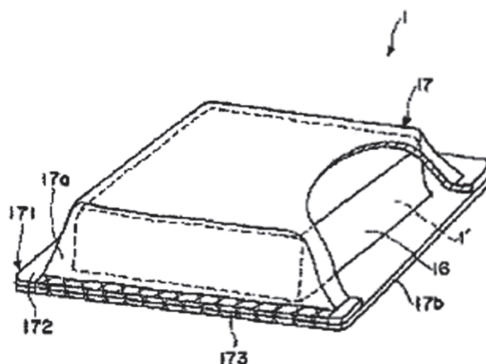
115. As seen in annotated Figure 1 below, Imai discloses a catheter kit, including a multi-compartmented single layer catheter tray 200 that stores equipment of the kit, such as syringes 12 in a first compartment (232), a catheter in a second compartment (233), and cotton balls in a third compartment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



116. 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.)

117. 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]



118. 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.)

6. U.S. Patent No. 5,931,303 to Salvadori (“Salvadori”)

119. 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.)

120. I understand that, because Salvadori issued on August 3, 1999, more than one year prior to the earliest alleged priority date of the '347 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

121. 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:

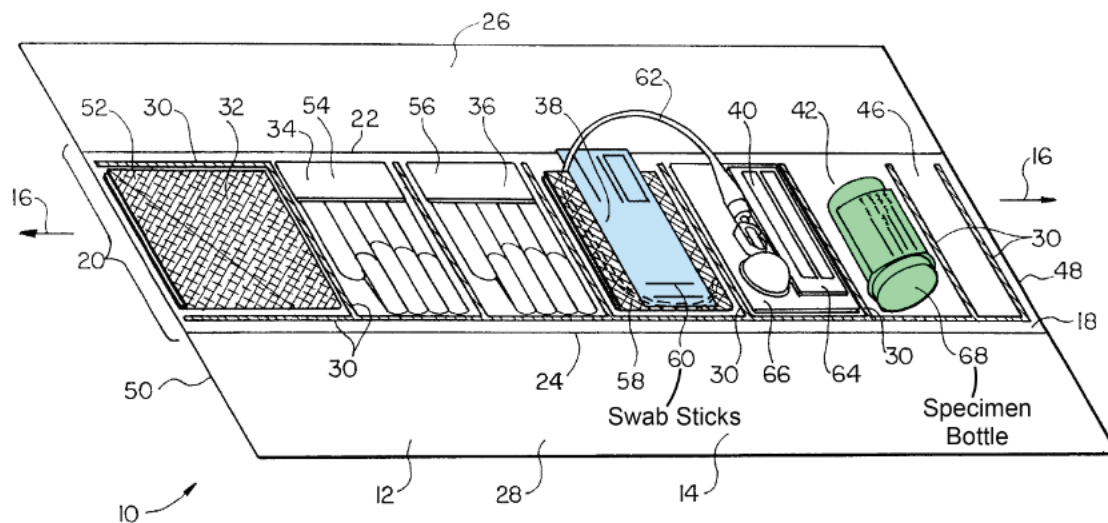


FIG. 1

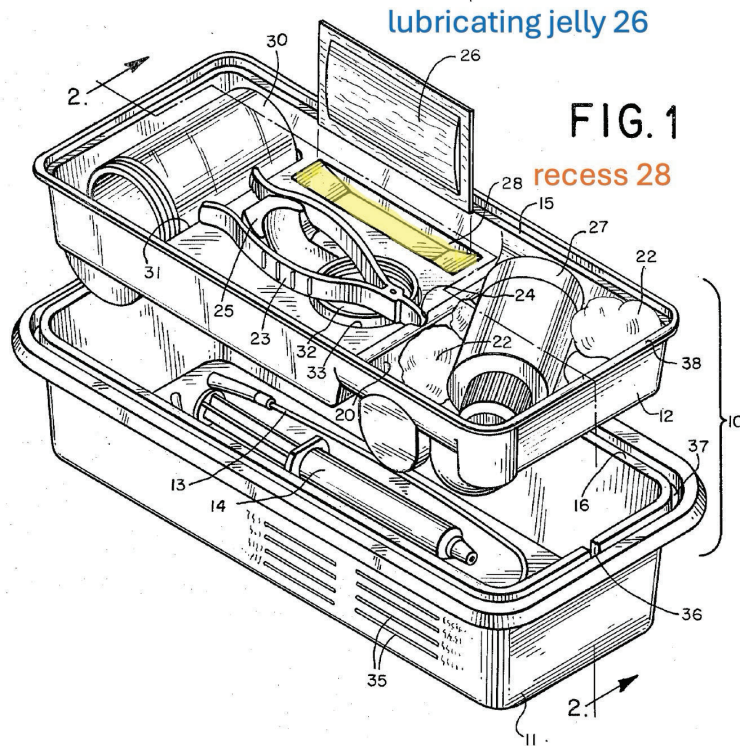
(Ex. 1013 at Fig. 1; 3:3-4.)

7. U.S. Patent No. 4,226,328 to Beddow (“Beddow”)

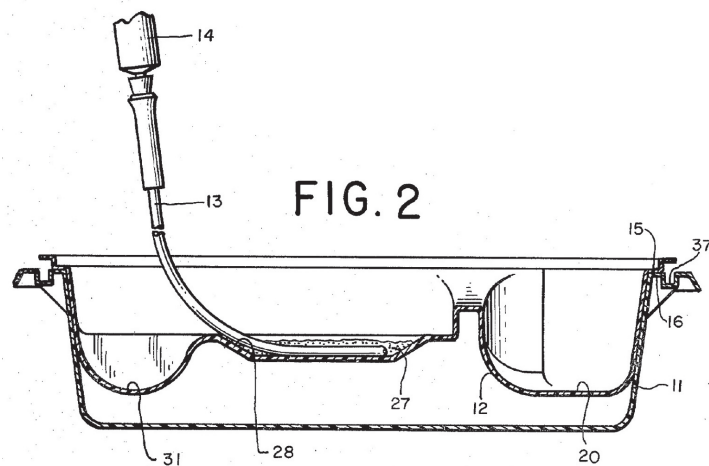
122. I understand that U.S. Patent No. 4,226,328 was issued to David V. Beddow. As indicated on the face of the patent, it issued on October 7, 1980. (Ex. 1010.)

123. I understand that, because Beddow issued on October 7, 1980, more than one year prior to the earliest alleged priority date of the '347 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

124. 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)



125. 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)

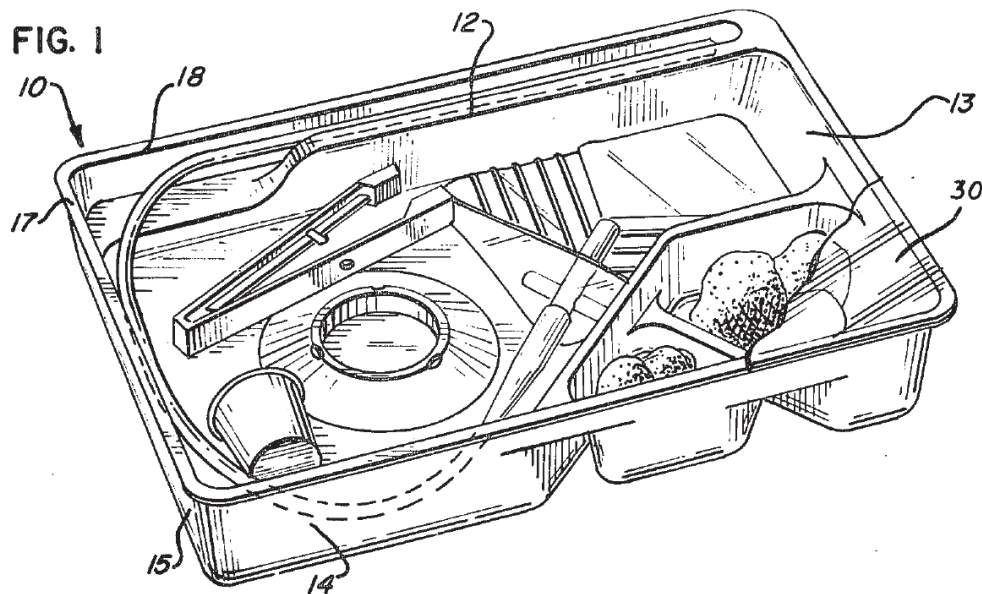
126. Beddow includes a wrap folded around tray between the tray and the outer “pouch.” (Ex. 1010 at 2:34-50.) The outer pouch, which “may be formed of a transparent and flexible plastic film,” “is sealed to maintain the sterility of the components within the catheterization package.” (Ex. 1010 at 2:34-50.)

**8. U.S. Patent No. 4,160,505 to Rauschenberger
 (“Rauschenberger”)**

127. 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.)

128. I understand that, because Rauschenberger issued on July 10, 1979, more than one year prior to the earliest alleged priority date of the ’347 patent (June 3, 2009), it is prior art under at least pre-AIA 35 U.S.C. § 102(b).

129. 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:

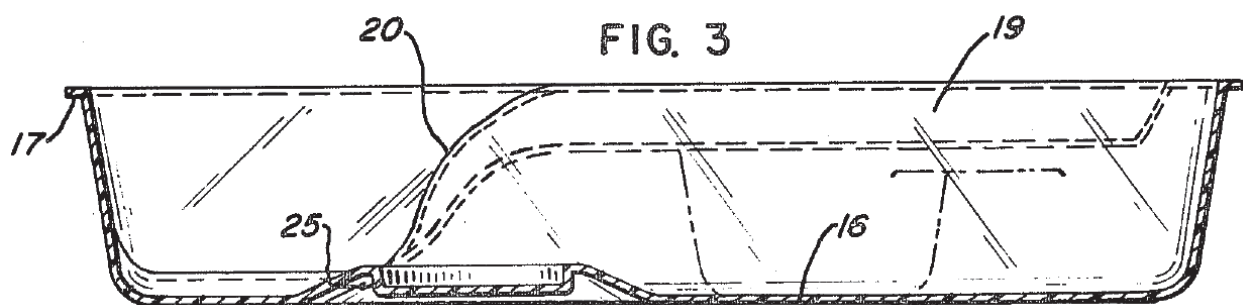


130. Rauschenberger notes that prior art trays (i.e., trays from before 1977) included CSR wraps and that steps of the catheterization procedure were performed on the CSR wrap such as the lubrication of the catheter and the application of antiseptic solution to pads. (Ex. 1021 at 1:8-26.) Rauschenberger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

131. 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.)

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



9. Nursing Standard Article

133. 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.)

134. 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).

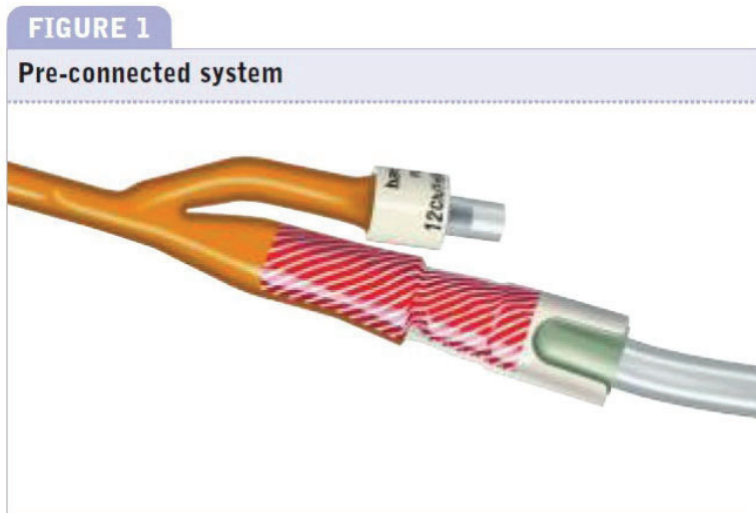
135. I have seen no evidence that the ’347 patent is entitled to an earlier priority date than the date of its patent application. To the extent Medline were to attempt to swear behind Nursing Standard, it would not change any of my opinions in my report. First, Nursing Standard is not explicitly used 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 ’347 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.

136. 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:

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.)



137. 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.)

138. 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.)

10. Male Catheter Insertion YouTube Video (“Catheterization Video”)

139. 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.

140. 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).

141. 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.

142. 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.



143. 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.)

144. 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.)

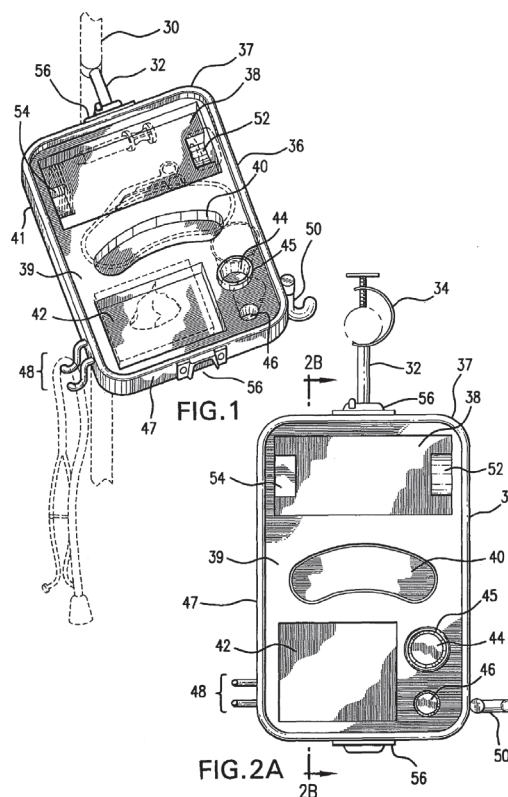
145. Accordingly, the Catheterization Video further shows that it was common to include two syringes in Foley catheter kits (to lubricate the catheter and inflate the retention balloon) more than one year before June 3, 2009.

11. U.S. Patent No. 7,967,137 to Fulbrook (“Fulbrook”)

146. 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.)

147. I understand that, because Fulbrook was filed more than one year prior to the earliest alleged priority date of the '347 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 '347 patent.

148. 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:



149. 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.)

150. 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.)

X. GROUNDS

A. Identification of Grounds

151. The following grounds are presented below.

Ground	35 U.S.C. § ¹	Claims	Prior Art References
1	103(a)	1, 2, 5, 7, 8, 14, 17	Solazzo, Serany, Disston, Imai
2	103(a)	6, 10, 11, 13, 15, 16, 18, 19	Solazzo, Serany, Disston, Imai, Salvadori
3	103(a)	1, 2, 5, 7, 8	Numata, Serany, Disston
4	103(a)	3, 4	Numata, Serany, Disston, Beddow
5	103(a)	6, 10, 11, 13	Numata, Serany, Disston, Salvadori
6	103(a)	14	Numata, Serany, Disston, Imai
7	103(a)	15-16	Numata, Serany, Disston, Imai, Salvadori
8	103(a)	17-20	Numata, Serany, Disston, Imai, Salvadori, Beddow

A. Ground 1: Obviousness Over Solazzo, Serany, Disston, and Imai

1. Independent Claim 1

(a) Limitations 1[p] and 1[a]

152. Solazzo discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*”

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

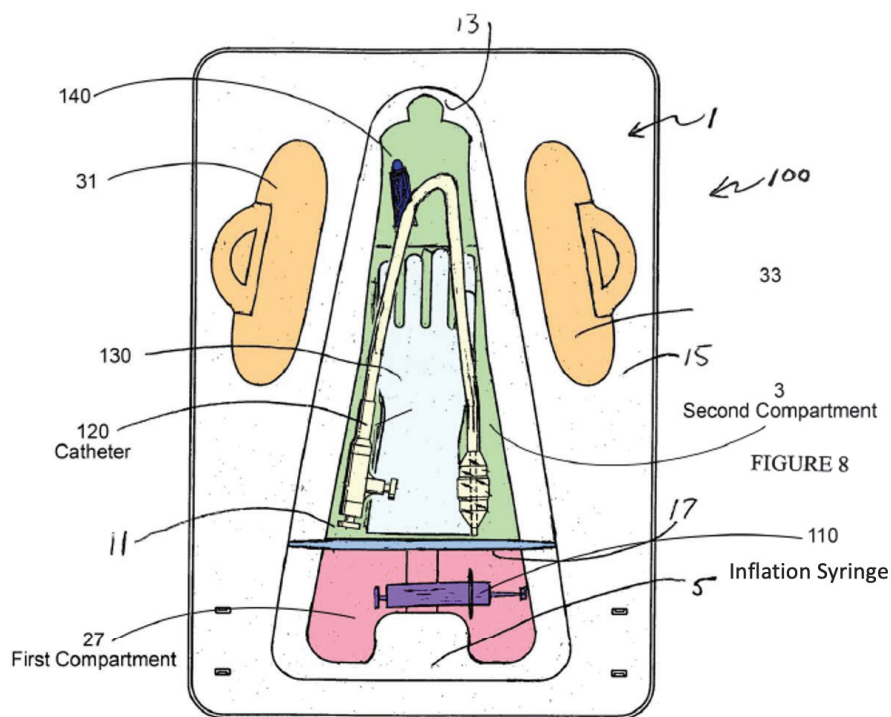


Urological Catheterization/Irrigation Tray.” Solazzo further states: “The present invention relates to an ergonomic urological catheterization/irrigation tray.” (Ex. 1005 at 2:35-36.)

155. 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)

156. Additionally, either of “Foley catheter lubricating wells 31 or 33 is a third compartment.” (Ex. 1005, 4:21-25.) Solazzo uses the terms “compartment” and “well” interchangeably. For example, it refers to compartments 3 and 27 both as “compartments” and alternatively as an “irrigation well” and “drainage well.” (Ex. 1005, 4:15-20 and 5:12-15 (claim 3).)

157. “[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:



158. As shown in Figure 8 above, 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.)

159. While first compartment 27 stores at least the inflation syringe—the location of the irrigation syringe is not provided—it would have been obvious to group multiple syringes in the first compartment for the reasons at claim 1[b] below.

160. While second compartment 3 stores a medical assembly (Foley catheter 120), it further would have been obvious to dispose a closed-system Foley catheter (also a medical assembly) in the second compartment of Solazzo in view of Serany/Disston for the reasons at limitation 1[c] below.

161. I note that the PTAB previously found an identical claim limitation disclosed by the same prior art: Solazzo, Serany, and Disston. (Ex. 1015 at 15-17.)

(b) Limitation 1[b]

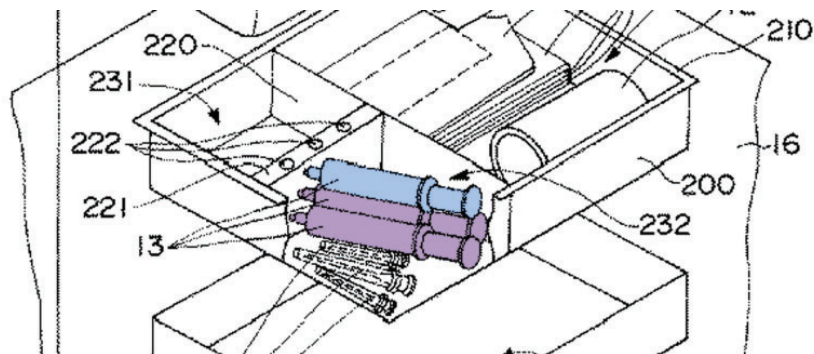
162. Solazzo in view of Serany and Imai discloses: “*a first syringe and a second syringe disposed within the first compartment.*”

163. Solazzo discloses “[t]he kit includes” both “an inflation syringe” and “an irrigation syringe.” (Ex. 1005, 3:15-24.) As discussed at limitation 1[a] 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.”)

164. 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 1[d]. It would have been obvious to also store the lubricant syringe in compartment 27 because it already holds the inflation syringe.

165. 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 syringes 13 in the same compartment of a catheter tray:



(Ex. 1012 at Figure 1; ¶¶ 0028, 0031.) Further illustrating that such grouping was well-known in the field of catheter kits, Numata also discloses storing three syringes in the same compartment as discussed at Ground, claim 1[b]. (Ex. 1008 at Fig. 4.)

166. Solazzo and Serany 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. 1009 at Fig. 6; 3:1-45.) 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.

167. 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)

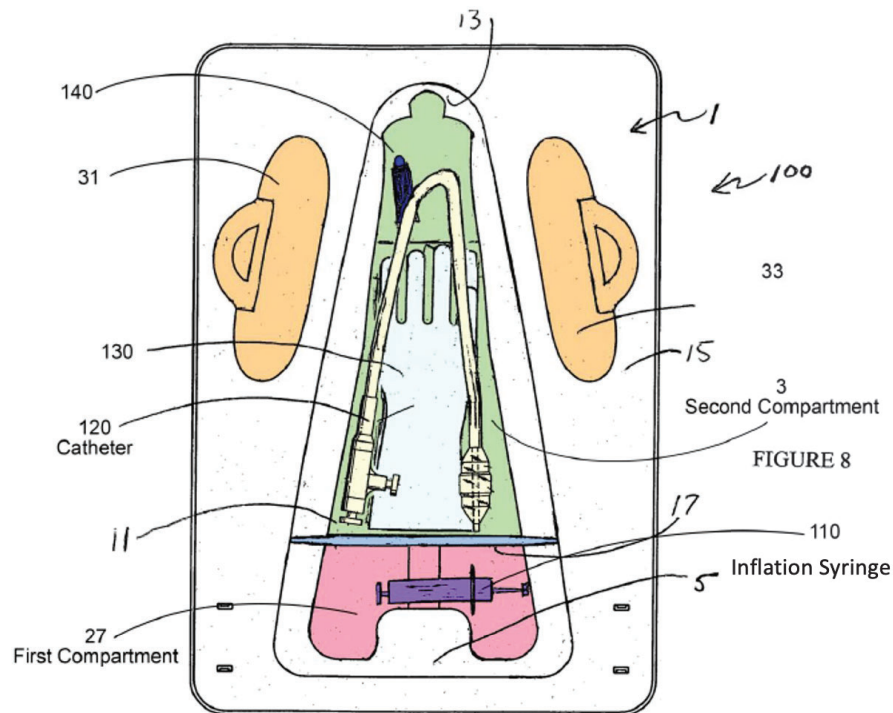
168. Finally, it would have been obvious to try grouping the syringes in the same compartment given the finite number of identified, predictable solutions (i.e., storing the syringes in separate compartments or the same compartment) with a reasonable expectation of success.

169. 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.

(c) Limitation 1[c]

170. Solazzo in view of Serany and Disston discloses “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*”

171. 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.)



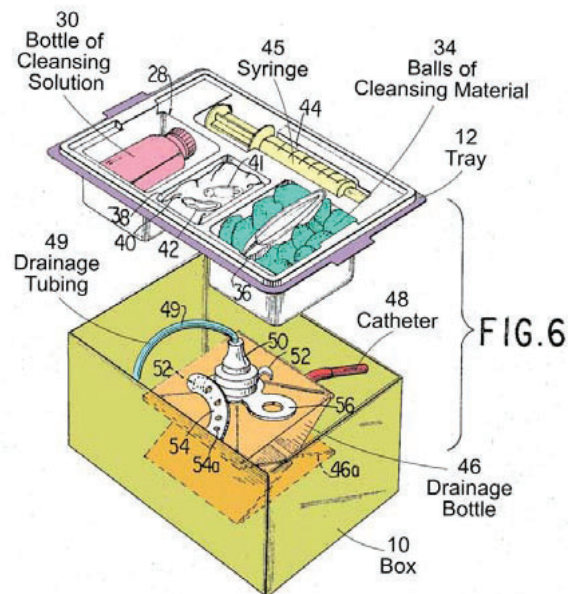
172. Solazzo also discloses “evacuation tubing,” and notes that “[d]rain 19 may be connected to flexible tubing and into a receiving receptance”. (Solazzo at 3:15-24; 4:10-15.)

173. 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.

174. A Foley catheter is an indwelling catheter that includes a balloon to retain the catheter in the patient for longer periods of times. 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.

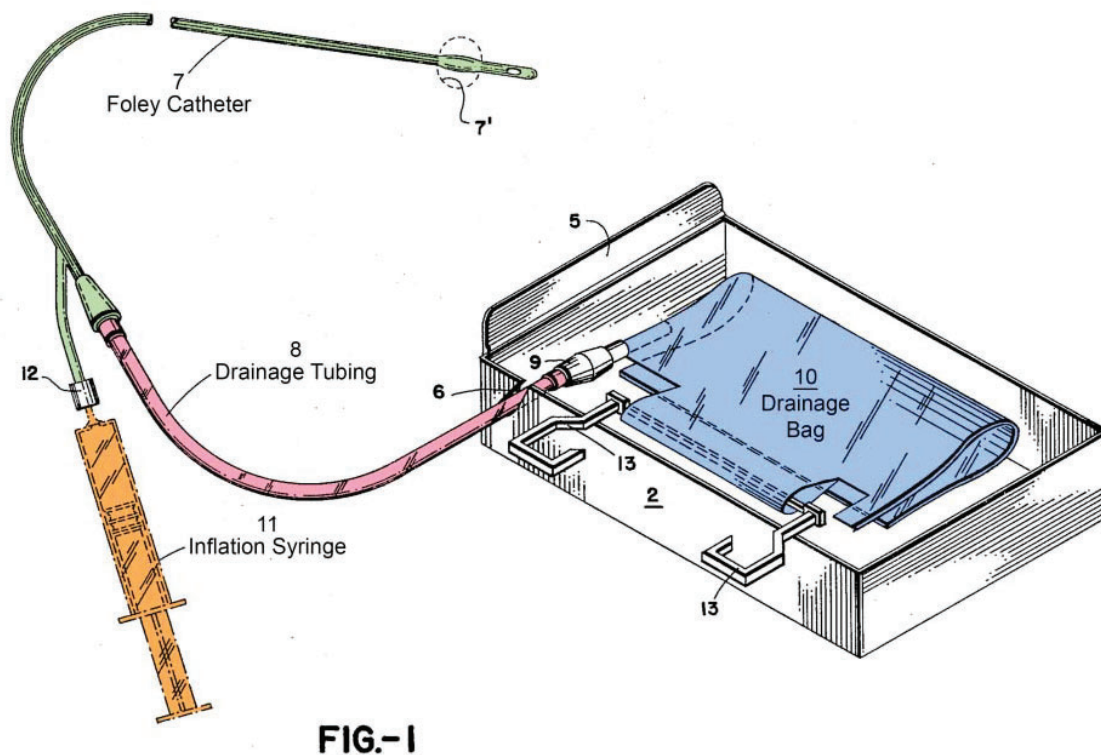
175. Serany discloses a closed-system Foley catheter, which is a medical assembly that “comprises a coiled tubing coupled between a fluid drain bag and a

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.



176. 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.

177. 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.)



178. 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 depended 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.

179. 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.

180. 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 tray 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.

181. 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.”

182. 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.

183. 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.)

(d) Limitation 1[d]

184. Solazzo in view of Serany discloses “*wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water.*”

185. **Lubricating Jelly.** 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, 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.

186. 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.)

187. 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.

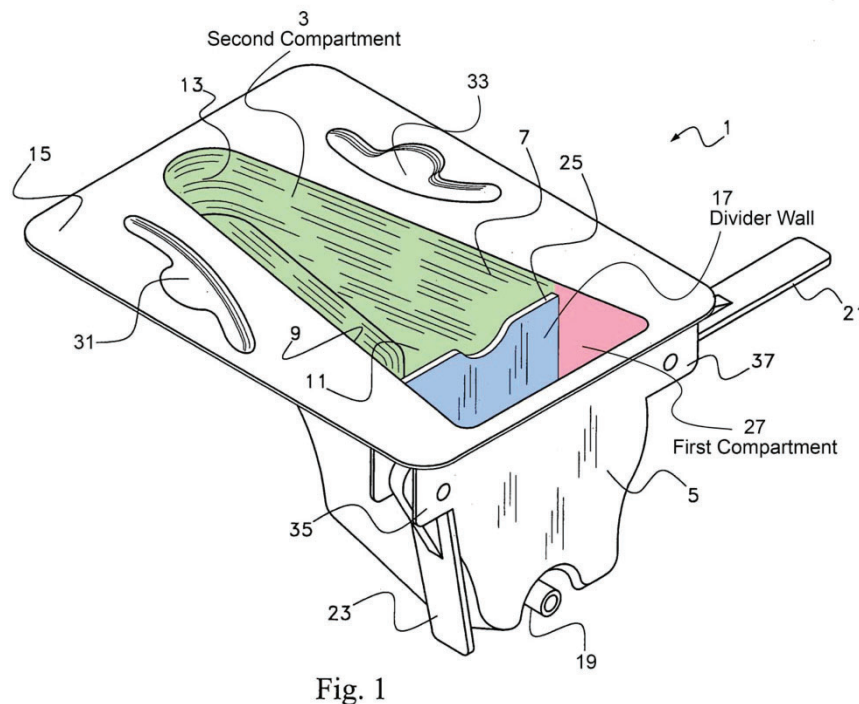
(Ex. 1023 at 17-18.)

188. **Water Syringe.** Solazzo discloses: "[t]he kit includes: ... (e.) an inflation syringe for inflation of a catheter with fluid." (Ex. 1005, 1:15-21). In the background, Solazzo mentions "a syringe prefilled with bacteriostatic water" because it was known in the art that an inflation syringe includes sterile water. (Ex. 1005, 1:38-42.) Thus, a POSA would understand that the "fluid" in the inflation syringe of Solazzo is sterile water because it was understood that the retention balloon to the Foley catheter is inside the patient and that sterile water should be used to the inflate the water. Serany also discloses an inflation syringe with "sterile

water”—confirming the ubiquitous use of sterile water in inflation syringes. (Ex. 1009, 3:50-51.)

(e) Limitation 1[e]

189. Solazzo discloses “wherein the first compartment and the second compartment are adjacent and separated by a barrier.” As shown in Figure 1 below, Solazzo’s first compartment 27 and second compartment 3 are adjacent and separated by a barrier (divider wall 17) “that creates two separate compartments”:



(Ex. 1005, Fig. 1, 4:15-16; 5:12-15)

190. Divider wall 17 is a “barrier” because it is a structure that prevents or blocks movement from or access between one compartment to another. Specifically, as described by Solazzo, the “divider wall creat[es] two separate compartments to

create an irrigation well and drainage well.” (Ex. 1005 at 5:12-15.) Thus, a POSA would understand that the divider wall is a barrier as prevents liquids from moving from to one compartment to the other. (Ex. 1005 at 5:12-15; 4:15-20 (noting how the divider wall will hold liquids in compartment until it reaches the top of the divider wall).)

191. Solazzo in view of Serany, Disston, and Imai therefore renders claim 1 obvious.

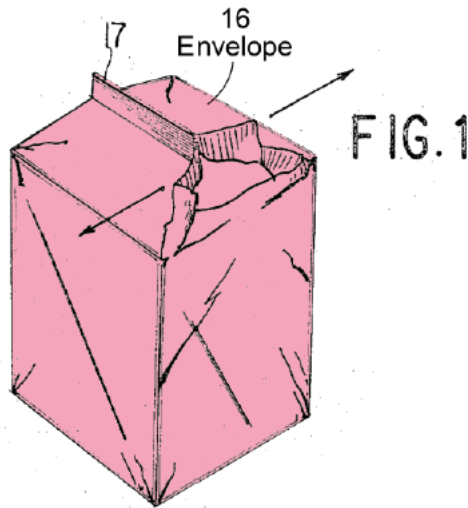
2. Claim 2

192. Solazzo in view of Serany disclose “*an outer packaging disposed about the single layer tray.*”

193. 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.

194. 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.

195. 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:



(Ex. 1009, Fig. 1.)

196. 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).)

197. 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.)

198. 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.

199. 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.

200. 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.)

201. Solazzo in view of Serany, Disston, and Imai therefore renders claim 2 obvious.

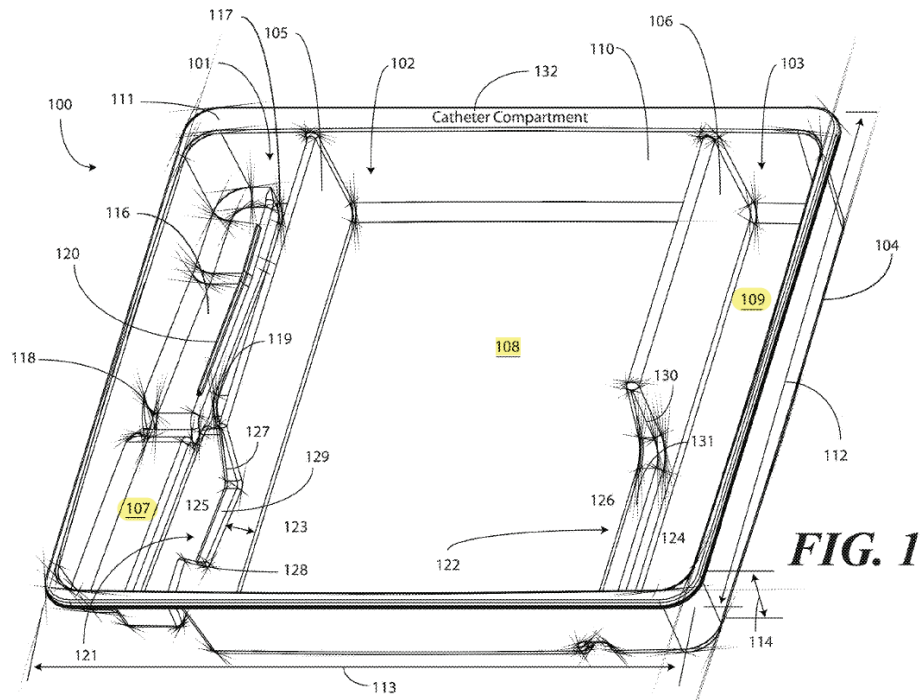
3. Claim 5

202. For the reasons at claim 1[d], Solazzo discloses "*wherein the water is sterile.*" Solazzo in view of Serany, Disston, and Imai therefore renders claim 5 obvious.

4. Claim 7

203. Solazzo discloses "*wherein the first compartment is bounded by a first base member and the second compartment is bounded by a second base member.*"

204. Initially, a brief discussion of the '347 patent's use of the term “base member” is warranted. The '347 patent discloses a tray with a **first compartment base member 107**, a **second compartment base member 108**, and a **third compartment base member 109**. (Ex. 1001 at 4:65-5:2 (emphases added), Fig.1)



205. These compartment “base members” are the bottom surfaces of each respective compartment as shown in Figure 1 above. The '347 patent teaches that bottom surface of each compartment is a single “compartment base member” regardless of sloping of the bottom surface. For example, the first compartment of the tray shown in Figure 1 has a **single** “first compartment base member 107” even though the bottom surface has multiple, inclined “stair-stepped” surfaces as shown in Figure 5:

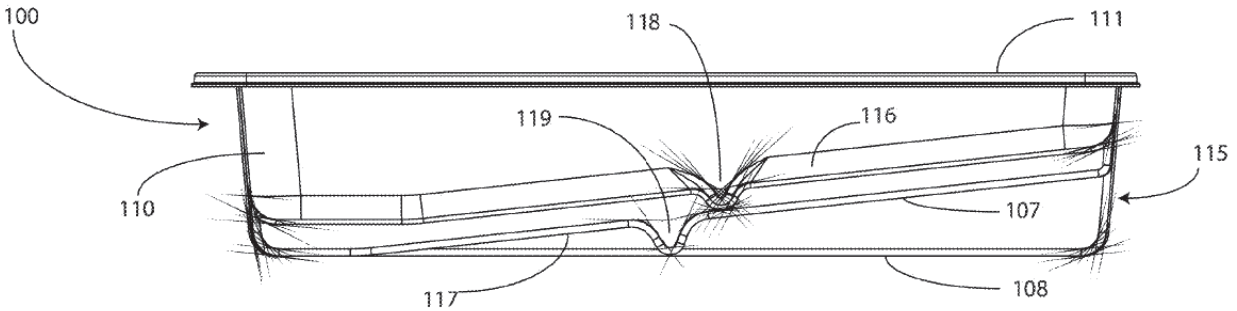
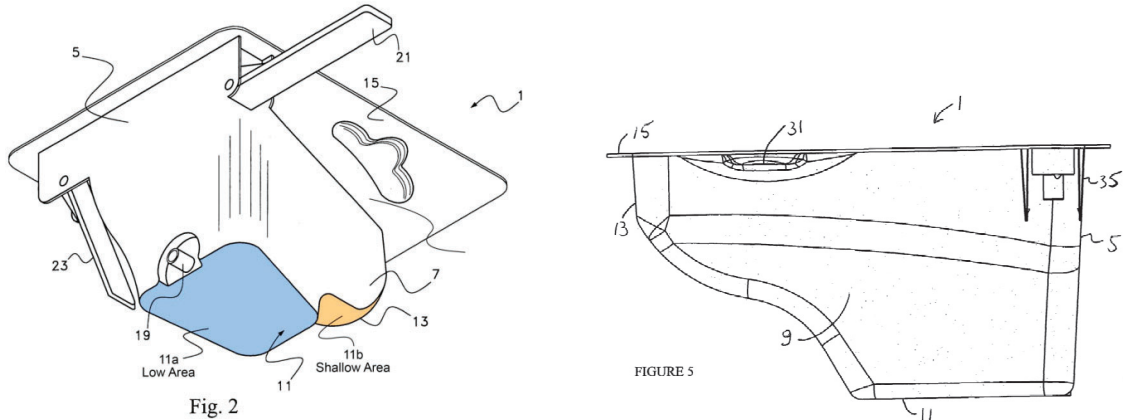


FIG. 5

206. Like the '347 patent, Solazzo discloses compartment base members that are both flat and inclined. Specifically, “bottom 11 has terraced arrangement with low area 11A and shallow area 11B (FIG. 2).” (Ex. 1005, 3:63-66.) Figures 2 and 5 shows bottom 11:



(Ex. 1005 at Figs. 2, 5.)

207. Therefore, low area 11A is a first compartment base member and a second compartment base member because it bounds all of first compartment 27 and a portion of second compartment 3. (Ex. 1005, 3:63-66; Figs. 1, 2, 8.) When viewing

because as seen in Figure 1 the slope ends before it reaches the divider wal.:

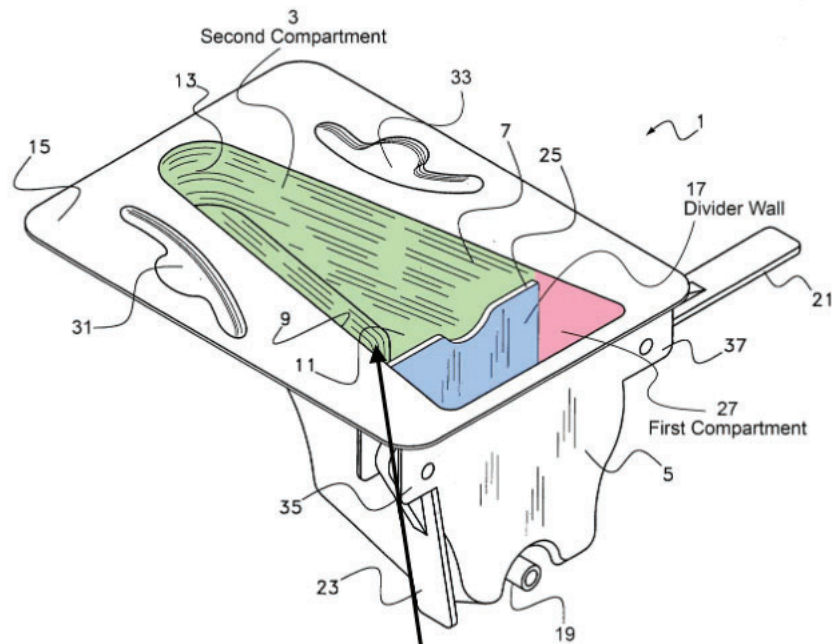


Fig. 1

end of slope

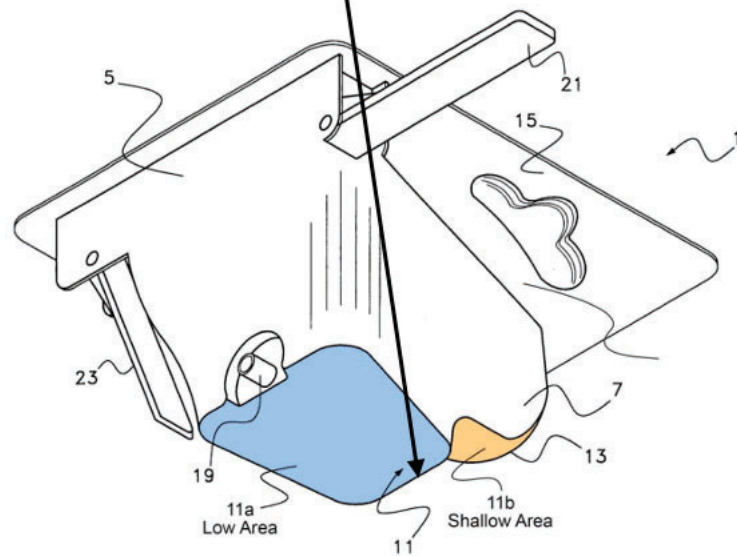
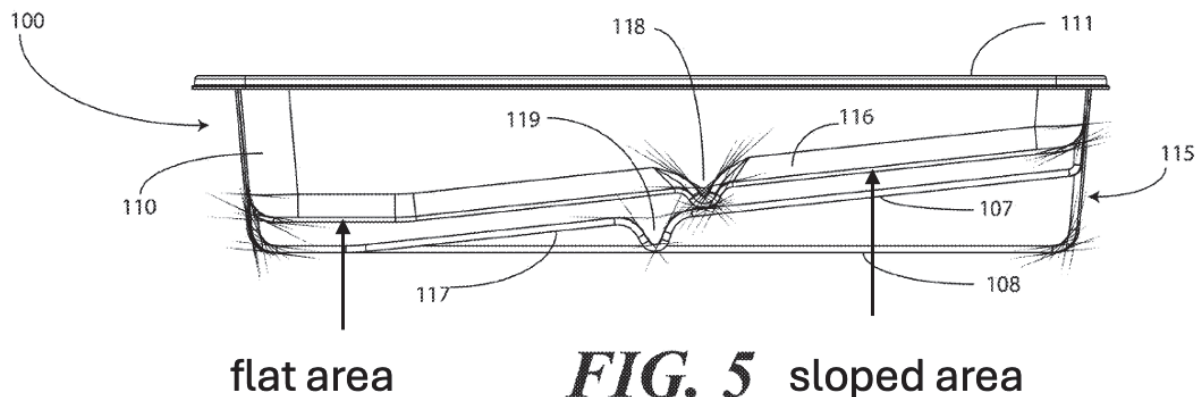


Fig. 2

208. Shallow area 11b is also a second compartment base member as it bounds the remaining portion of second compartment 3. This means the second base member (i.e., bottom surface of the second compartment) includes both a portion of low area 11A and shallow area 11B. The fact that 11B has a “non constant depth” is entirely consistent with the ’347 patent, as shown in the annotated Figure below as it discloses an *inclined, stair-stepped first compartment base member* with both a “first step portion 116” and a “second step portion 117.” (Ex. 1005 at 3:63-65; Ex. 1001 at Fig. 5; 5:49-61.)



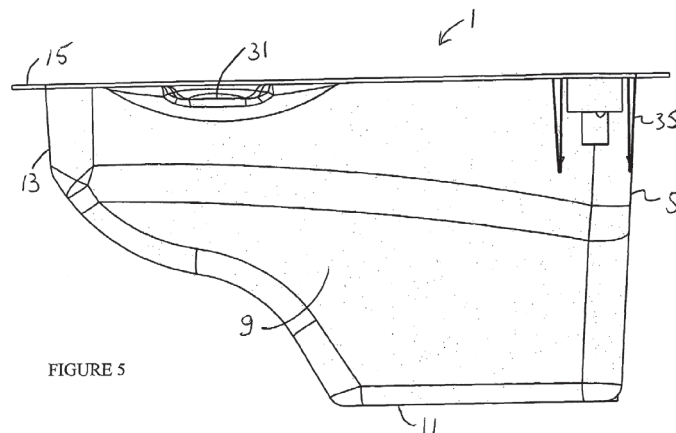
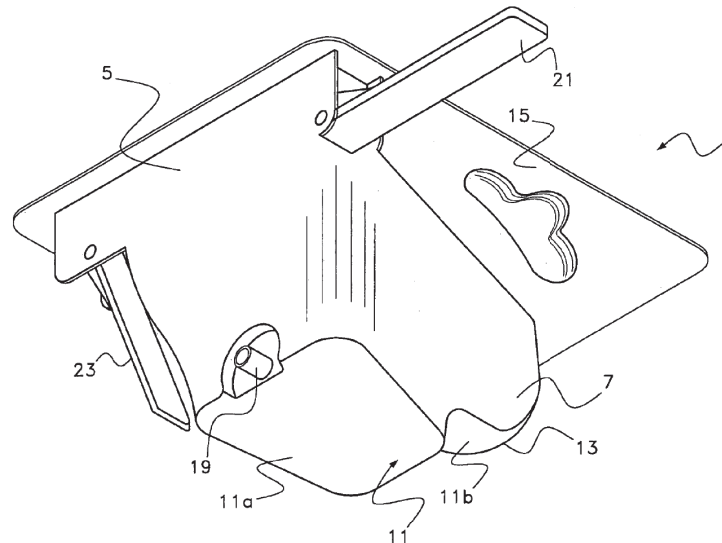
209. In sum, Solazzo discloses the first compartment is bounded by a first base member (bottom 11, and more specifically a portion of low area 11A) and the second compartment is bounded by a second base member (bottom 11, and more specifically both shallow area 11B and a portion of low area 11A.)

210. Solazzo in view of Serany, Disston, and Imai therefore renders claim 7 obvious.

5. Claim 8

211. Solazzo discloses “*wherein a portion of the first base member and another portion of the second base member are substantially coplanar.*”

212. For the reasons at claim 7, the first base member is formed by a portion of low area 11A and the second base member is formed by the remaining portion of 11A and a portion of shallow area 11B. As shown in Figures 2 and 5 below, 11A is substantially coplanar because the surface lies on the same plane:



213. I understand that the Board previously concluded that 11A is not inclined. (IPR2019-00035, Paper 73 at 23.) Even if low area 11A were inclined (contrary to the Board’s previous finding), it would have been obvious to a POSA for low area 11A to be flat as it was well-known technique for a tray to include a flat bottom surface so that when the tray is set down it is stable and not prone to easily tipping over, for example, as shown by Disston, Serany, and Imai, all of which include trays with flat bottom surfaces. (Ex. 1009 at Fig. 6, Ex. 1008 at Figs. 1-2; Ex. 1012 at Fig. 1.)

214. Solazzo in view of Serany, Disston, and Imai therefore renders claim 8 obvious.

6. Independent Claim 14

(a) Limitations 14[p] and 14[a]

215. For the reasons in limitation 1[a], Solazzo discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*”

(b) Limitation 14[b]

216. For the reasons in limitation 1[b], Solazzo in view of Serany and Imai discloses “*a first syringe and a second syringe disposed within the first compartment.*”

(c) Limitation 14[c]

217. For the reasons in limitation 1[c], Solazzo in view of Serany and Disston discloses “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*”

(d) Limitation 14[d]

218. For the reasons in limitation 1[d], Solazzo in view of Serany discloses “*wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water.*”

(e) Limitation 14[e]

219. For the reasons at limitation 1[e], Solazzo discloses “*the first compartment and the second compartment are adjacent and separated by a barrier.*”

(f) Limitation 14[f]

220. Solazzo in view of Serany and Imai discloses “the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a 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.*)

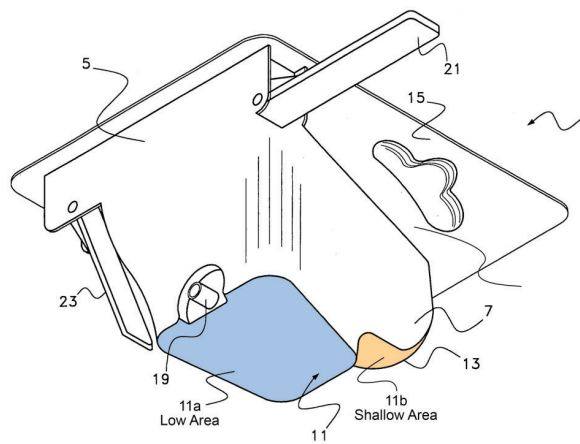


Fig. 2

221. This arrangement (lubricant above the inflation syringe) is consistent with the order of 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 design such that a test ballon were inflated, the arrangement of syringes could be reversed.

222. For the reasons at limitation 1[b], it would have been obvious to substitute the lubricant tube with a syringe and groups 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.)

223. 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.)

224. 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.

225. 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 discussed at limitation 14[g]). Alternatively, this order could be reversed if a test balloon step is performed as that instead requires using the water syringe first.

226. 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

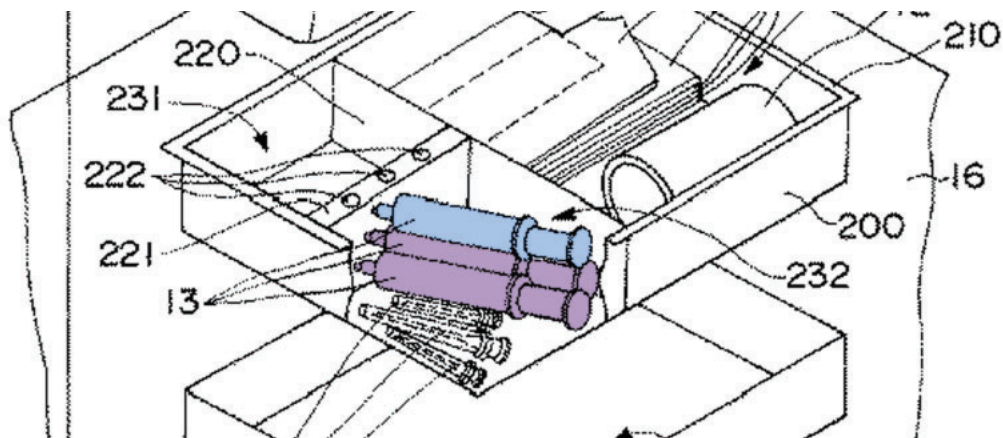
applies a known technique (arranging components in their order of use) to a known device (a catheter kit) ready for improvement to yield predictable results (arranging items in “a logical step-by-step order to facilitate the nurses or physicians task”).

227. Accordingly, the combination of Solazzo in view of Serany discloses this claim element. The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (Ex. 1014 at 35-36.)

(g) Limitation 14[g]

228. Claim 14[g] requires “the first compartment supports the first syringe and the second syringe at different heights.” Solazzo in view of Serany and Imai discloses “the first compartment supports the first syringe and the second syringe at different heights.”

229. As discussed at limitation 14[f], it would have been obvious to arrange syringes in their order of use. When arranging them in their order of use, it would have been obvious to try arranging them at different heights given the finite number of options available to arrange the syringes in such a manner (at different heights or left-to-right). Imai discloses stacking syringes in a catheter tray at different heights, which was a well-known way to arrange equipment, including syringes, within a tray. Thus, a POSA would have understood that when placing multiple syringes in compartment 27 in their order of use, the syringes could be stacked on top of each other in their order of use in compartment 27 in view of Imai and Serany:



(Ex. 1012 ¶ 0014; 0031; Fig. 1.) For example, as discussed at limitation 14[f], the syringes could be arranged with the lubricant syringe on the top (because it is used first) and the inflation and irrigation syringes below the lubricant syringe (as those are used later in the procedure).

230. A POSA would have been motivated to combine the packaging solution taught by Imai with the tray of Solazzo because it involves applying a known technique (stacking syringes at different heights) to a known device (a Foley catheter tray as shown by Solazzo) ready for improvement to yield predictable results (ordering components in a manner that is convenient for the user and to save space within the tray). Also, it would have been obvious to try stacking the syringe at different heights consistent with their order of use because there were a finite number of identified, predictable solutions (i.e., placing the syringes at the same height or stacking them at different heights) with a reasonable expectation of success (as stacking items within a tray was a well-known solution as shown by Imai).

231. I note that the PTAB previously found an identical claim limitation disclosed by the same prior art: Solazzo, Serany, and Imai. (Ex. 1015 at 35-36.)

232. Accordingly, Solazzo in view of Imai discloses this claim element. Solazzo in view of Serany, Disston, and Imai therefore renders claim 14 obvious.

7. Independent Claim 17

(a) Limitations 17[p] and 17[a]

233. Claim 17[a] requires “*A medical procedure kit, comprising: a surface defining a single layer tray having a first compartment adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.*”

234. For the reasons at limitation 1[p], Solazzo discloses “a medical procedure kit.” For the reasons at limitations 1[a] and [e], Solazzo discloses “*a single layer tray having a first compartment adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.*”

235. Solazzo also discloses (or at least renders obvious) “***a surface defining a single layer tray having a first compartment adjacent to and separated by a barrier from, a second compartment.***” Specifically, the surface of Solazzo that defines a single layer tray has multiple compartments, including a first compartment 27 adjacent to and separated by a barrier (divider wall 17) from a second compartment

3. (Ex. 1005, 2:48-51; 3:52-57; 4:15-16; Figs 1 & 8.) The tray and divider wall 17 are all formed from a single surface.

236. Solazzo does not expressly state how the tray is manufactured. At the time of the invention, both thermoforming and injection molding were well-known methods for manufacturing a tray such as the tray shown in Figure 1 of Solazzo, which includes multiple compartments and rounded edges. For example, as discussed below, Beddow's tray is formed from a single sheet (surface) of material with multiple compartments and is "thermoformed." (Ex. 1010 at 2:55-57; Fig. 1) As discussed at Section IX.11, Fulbrook's injection molded tray is also formed from a single sheet (surface) of material with multiple compartments. (Ex. 1029 at Figs. 1-5, Abstract; 3:61-62; 5:50-53; 11:61-64.)

237. A POSA would thus understand that the tray of Solazzo could be manufactured using either method. (*See also* IPR2019-00036, Ex. 2026 (Declaration of Medline's Expert Dr. Sher Paul Singh) ¶¶ 138-39 (noting "the manufacturing process used to manufacture products like Solazzo's tray from plastics would most likely be thermoforming or injection molding.")²

² To the extent Medline now argues that Solazzo could only be manufactured using one of these methods, it would have been obvious to try utilizing the other method as both injection molded and thermoforming were well-known methods for manufacturing at tray at the time of Solazzo's filing, and thus there were a finite number of options to choose from when manufacturing Solazzo's tray with a reasonable expectation of success.

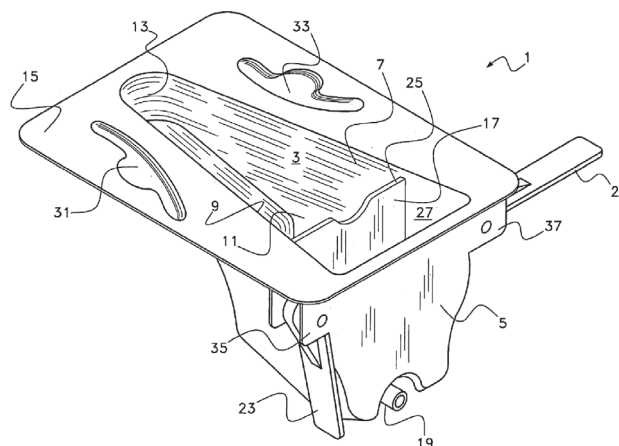


Fig. 1

238. Both thermoforming and injection molding allows for the tray, including the divider wall, to be integrally formed. I note that the specification of the '347 patent confirms that either a “thermally formed” or “injection molded” tray is appropriate for forming a “surface defining a single layer tray having a first compartment separated by a barrier from, a second compartment.” (Ex. 1001 at 4:39-50.) It was well-known when thermoforming a tray to form divider walls integrally with the tray. For example, Beddow discloses “The base and tray portions may be thermoformed by conventional methods from a thin plastic material.” (Ex. 1010 at 2:55-57.) A POSA viewing Figure 1 of Beddow would understand that its divider walls are integrally formed. (Ex. 1010 at Fig. 1.)

239. It was also well-known when using thermoforming to form barriers (i.e., internal tray walls) integrally with the tray. With respect to thermoforming, the tray and divider wall would almost certainly be formed from a single sheet (surface) of material. The alternative—using multiple molds to create separate components

and then needing to fasten the divider wall to the tray—would add manufacturing complexity (added assembly steps) resulting in a tray that is more expensive while also having reduced quality, such as higher risks for leaks between compartments. Thus, when using thermoforming, a POSA would understand that the divider wall 17 of Solazzo would (or, at a minimum, easily could) be integrally formed with the rest of the tray.

240. It was also well-known when using injection molding to form barriers (i.e., internal tray walls) integrally with the tray. As with thermoforming, such manufacturing techniques also have the advantage of allowing for a more durable tray while streamlining manufacturing (e.g., by using a single mold with multiple gates to avoid areas of high stress concentration in the tray.) (Ex. 1029 at 11:61-64 (noting that 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.”) I understand that Medline’s expert, Dr. Paul Sher Singh “testified that a different prior art single layer tray [Rauschenberger] that was formed by injection molding depicted a molded surface defining multiple compartments separated by a barrier.” (Ex. 1015 at 34.) I agree that a POSA would understand the tray of Rauschenberger is formed from a single contoured surface that defines the compartments of the tray, including the divider walls, and the tray could be formed from injection molding. (Ex. 1021 at

Figs. 1-3; 1:50-61.) Additionally, Fulbrook is another example of single layer medical device tray that is injection molded and includes multiple compartments to store components such as syringes that is formed from a single surface. (Ex. 1029 at Figs. 1-5, Abstract; 3:61-62; 5:50-53; 11:61-64.) Thus, when using injection molding, a POSA would understand that the divider wall 17 of Solazzo would (or, at a minimum, easily could) be integrally formed with the rest of the tray.

241. I understand that Medline's expert testified in a previous IPR proceeding that divider wall 17 is not formed from a single contoured surface. However, I understand his conclusion was driven by an understanding that Solazzo's reference to "divider wall 17" as "optional" means the divider wall is a "separate piece" that is removable. (IPR2019-00036, Ex. 2026 ¶¶ 138-39.) I disagree that the divider wall is removable. Initially, I discern no benefit (and Solazzo does not provide one) as to why the user of Solazzo would want to remove the divider wall during operation of the tray. To the contrary, Solazzo states that divider wall separates compartments 3 and 17 into a "drainage well and irrigation well." (Solazzo at 5:12-15.) Making the divider wall 17 removable would raise the risk of inadvertent contamination of the irrigation well if the user were to remove the wall as urine could contaminate the irrigation well. It is also unnecessary since Solazzo's divider wall is already designed to allow overflow (if necessary) between compartments (Ex. 1005, 4:15-20.) Thus, I understand "optional" to instead

described two different embodiments of Solazzo: a tray with a divider wall and a tray without a divider wall. I understand that the Board previously agreed that Solazzo's divider wall is not removeable: "Solazzo implies that divider wall 17 is integrally formed with the adjacent compartments 3 and 27 because divider wall 17 prevents fluid from crossing the wall unless the fluid overflows the top of the wall." (Ex. 1015 at 34 (citing Ex. 1005, 4:15–20).)

242. Finally, I understand the Board considered a substantively identical limitation in claim 61 of the '088 patent and found that Solazzo disclosed it. (Ex. 1015 at 30-35.)

243. To the extent that Solazzo does not expressly disclose an integrally formed barrier, it would have been obvious to a POSA to form divider wall 17 integrally with the surface of the single layer tray, as noted above. This applies a known technique (forming an internal divider wall integrally using known manufacturing methods) to a known device (a catheter kit) to yield predictable results (allowing for the efficient manufacture of a robust tray).

244. I note that Dr. Singh in the previous IPR testified that "forming the divider wall out of a separate piece would be reasonable and a cost-effective solution." (IPR2019-00036, Ex. 2026 ¶¶ 138-39.) This appears to be an argument for why it would have been obvious to form the divider wall out of a separate piece. Even if forming it separately was obvious, by the same notion forming the divider

wall integrally with the tray would also have been obvious as it also would have been a reasonable and equal (if not a more) cost-effective solution. Thus, it would have been obvious to try given the finite number of identified predictable solutions (forming the divider wall integrally versus as a separate piece.)

245. A POSA would also have been motivated to form the divider wall integrally because it is the *more* reasonable and cost-effective solution than a separate piece for the reasons below. *First*, an integral divider wall will strengthen the tray allowing it to be stiffer and maintain its shape. A divider wall as a separate piece may provide some reinforcement but not as much as if the divider wall is integrally formed. *Second*, if the divider wall is a separate piece then multiple molds will be required for both the tray and the divider wall instead of a single mold—adding cost and complexity.³ Additionally, an additionally manufacturing step will be required to add the divider wall to the tray. This would reduce manufacturing complexity (fewer assembly steps) and reduce potential quality issues, such as reduce the risk of leaking (due to incomplete bonds or mismatch of parts). In sum, a POSA would understand that forming the divider wall separately would be a more

³ Designing the mold to include an internal divider wall may require a more complex mold but designing such a mold is a one-time cost. In contrast, manufacturing parts using two different molds and adding a separate piece to the tray is a repeated cost. Thus, any additional upfront costs of an integral divider wall would likely be dwarfed by ongoing costs of a separate piece solution.

costly solution than forming the piece separately. *Third*, a divider wall as a separate piece would be more prone to leaking, which could result in contamination of the irrigation well by a divider wall. Thus, a POSA would have been strongly motivated to form Solazzo's divider wall integrally with the tray.

(b) Limitation 17[b]

246. Claim 17[b] requires “*a first syringe and a second syringe disposed within the first compartment, the first syringe containing lubricating jelly and the second syringe containing water, wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure.*”

247. For the reasons in limitation 1[b], Solazzo in view of Serany and Imai discloses “*a first syringe and a second syringe disposed within the first compartment.*”

248. For the reasons in limitation 1[d], Solazzo discloses “*the first syringe containing lubricating jelly and the second syringe containing water.*”

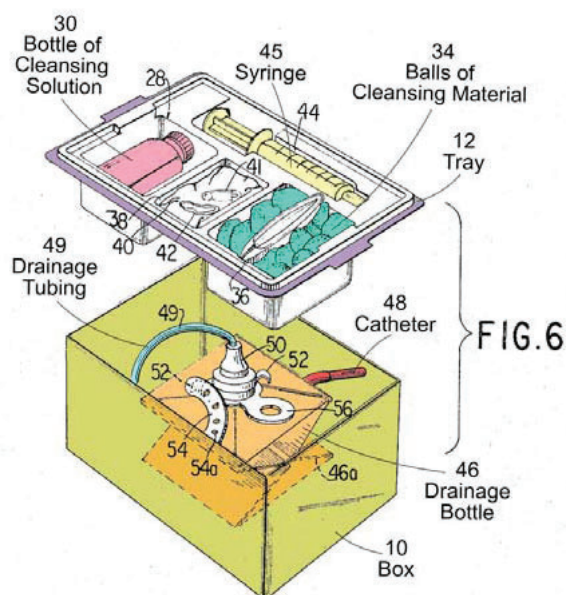
249. For the reasons in limitations 14[f] and [g], Solazzo in view of Serany and Imai discloses “*wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure.*”

(c) Limitation 17[c]

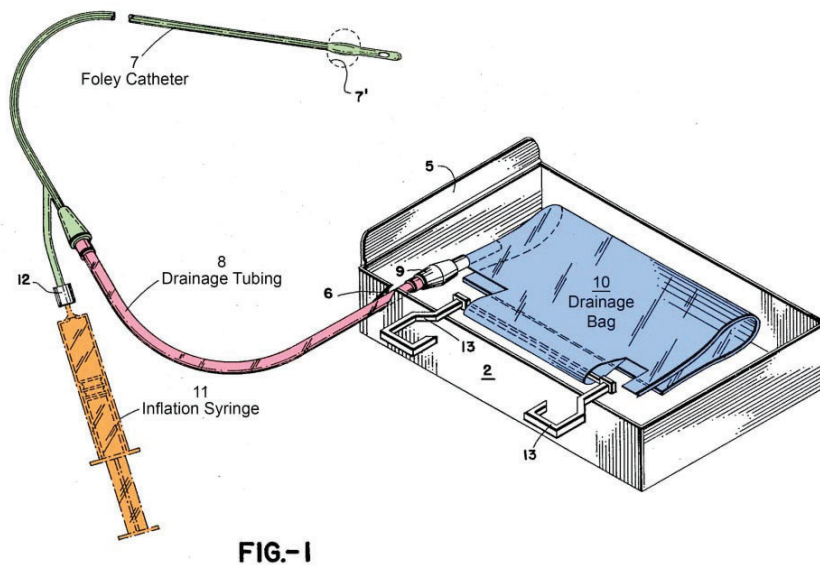
250. Claim 17[c] requires “*the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment with the coiled tubing positioned between the Foley catheter and the fluid drain bag.*”

251. For the reasons at limitation 1[c], Solazzo in view of Serany and Disston disclose “*the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment.*”

252. Serany discloses “with the coiled tubing positioned between the Foley catheter and the fluid drain bag.” Specifically, Serany discloses that “drainage tubing 49” “connect[s]” the “catheter 48” to the “bottle 46” as shown in Figure 6 and there is “between” these parts. (Ex. 1009 at 3:32-35.)



253. Disston also discloses drainage tube 8 positioned between catheter 7 and drainage bag 10 as shown in Figure 1 below:



(Ex. 1008 at 2:19-23.)

254. To the extent Medline were to argue that “positioned between” requires the tubing to be arranged within the second compartment such that is positioned above the drainage bag and below the Foley catheter when situated in the second compartment, Solazzo in view of Serany and Disston still discloses this claim element.

255. As discussed at limitation 1[c], both Serany and Disston disclose storing the catheter, tubing, and catheter together with the tubing connecting the catheter and bag. As shown in Figure 6 of Serany, the collapsible drainage bag is at

the bottom of box 10 (and “folded flat” when stored) so the drainage tubing 49 is thus necessarily positioned above it when stored. (Ex. 1009 at Fig. 6, 3:29-34.) The positioning of the Foley catheter is not entirely clear given only a portion of it is visible in Figure 6. However, it is connected to the drainage bag via the drainage tubing 49 so it too must be above the drainage bag, which is “folded flat” at the bottom of box 10. (Ex. 1009 at Fig. 6, 3:29-34.) Additionally, Serany states: “the catheter 48 is lubricated with the lubricating jelly 40 while the drainage bottle 46 and tubing 49 are still in the box 10.” (Ex. 1009 at 3:45-48.) A POSA would thus understand that Serany’s catheter would have been placed on top of the tubing, which is further on top of the drainage bag, given that the catheter is removed from the box 10 before the drainage tubing. Such an arraignment is consistent with Serany’s teaching of “everything [being] available in the proper order of use.” (Ex. 1009 at 1:23-25.)

256. When adding the closed-system Foley catheter of Serany/Disston to Solazzo, it would have been obvious to a POSITA to arrange the items of a closed-system Foley catheter in a top-to-bottom arrangement such that the drainage bag is on the bottom of the tray and the Foley catheter is provided on top with the coiled tubing positioned between them.

257. Serany provides motivation to arrange the items in this order by teaching arranging “components in their preferred order of use” and “proper order

of use.” (Ex. 1009, 1:9-12; 1:23-25.) The Foley catheter is necessarily used before the tubing and drainage receptacle. Specifically, a clinician needs access to the Foley catheter to lubricate and insert it before the tubing and drainage bag are accessed. Upon accessing and inserting the Foley catheter, some amount of the coiled tubing will also be accessed and removed from the tray as shown by Disston (Ex. 1008, Fig. 1.) Finally, the drainage bag is accessed last and attached to the bed as discussed by Serany and Disston. (Ex. 1009 at 3:45-57; Ex. 1008 at 2:53-55.) Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo “*with the coiled tubing positioned between the Foley catheter and the fluid drain bag*” (if this claim language requires such an arrangement).

258. I understand that the Federal Circuit already accepted Bard’s argument that it would have been obvious to place a drainage bag under the Foley catheter given their order of use:

Here, the limitation amounts to no more than rearranging simple items (a fluid receptacle and catheter) in a tray. Serany’s disclosure, coupled with common sense, would have provided a skilled artisan with ample motivation to place the fluid receptacle under the catheter; such an arrangement would conveniently place the items in the order they are used during the procedure.

C. R. Bard, 2021 WL 3574043, at *7.

259. By the same logic, it would have been obvious to position the coiled tubing between the Foley catheter and drainage bag as the tubing merely connects

the Foley catheter and bag. Similarly, I understand the Board also previously invalidated claim 14 of the related '400 Patent in view of Solazzo and Serany, which required “the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube.” (Ex. 1023 at 26-27.)

260. Accordingly, Solazzo in view of Serany and Disston discloses this claim element. Solazzo in view of Serany, Disston, and Imai therefore renders claim 17 obvious.

B. Ground 2: Obviousness Over Solazzo, Serany, Disston, Imai and Salvadori

1. Claim 6

261. Claim 6 requires “*a specimen jar disposed within the single layer tray.*” Salvadori is a urethral catheter kit that discloses “specimen bottle 68,” which a POSA would understand is a specimen jar as a “specimen jar” and a “specimen bottle” are interchangeable as they both refer to small, cylindrical containers that are used to collect a urine sample. (Ex. 1009, 1:12-16; 3:8; Figure 1.)

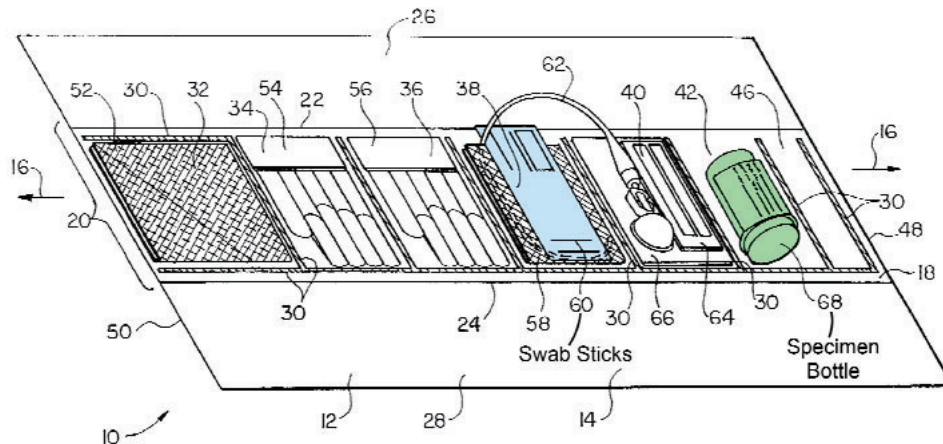


FIG. 1

262. Specimen jars were common in prior art catheter trays (as in Salvadori, Beddow, and Rauschenberger). (Ex. 1010, 1:21-25; Ex. 1013, 3:8; Ex. 1014, 1:21-25.) They are used to take a specimen of urine from a patient “if there is a clinical need to take a catheter specimen or urine.” (Ex. 1019, 51.)

263. In view of Salvadori, a POSA would have been motivated to include a specimen jar in the catheterization kit of Solazzo to allow a practitioner to take a urine sample when the clinical need arises, e.g., to run an assay of the urine to determine if the patient has a urinary tract infection.

264. This involves the use of a known technique (provision of a specimen jar) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (providing a specimen jar so that the practitioner can take a urine specimen when the patient is catheterized with the Foley catheter disclosed by Solazzo).

265. Finally, I note my understanding that the PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 23-24.)

266. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore renders claim 6 obvious.

2. Claims 10 and 15

267. Claims 10 and 15 recite identical limitations. They require “*an outer packaging disposed about the single layer tray; a Foley catheter securement device disposed within the single layer tray; and one or more swabsticks disposed within the single layer tray.*”

268. **Outer Packaging.** For the reasons stated for claim 2, Solazzo in view of Serany discloses “*an outer packaging disposed about the single layer tray.*” Accordingly, the combination of Solazzo in view of Serany discloses this claim element.

269. **Catheter Securement Device.** Solazzo in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

270. It would have been obvious to add a Foley catheter securement device to the kit of Solazzo as it was known to secure the catheter to the bed to minimize movement of the indwelling catheter, which could reduce the risk of infection. Nursing Standard notes (citing to 2002 and 2006 studies) that stabilizing the catheter

via a catheter securement device was a known technique that could reduce infection rates:

If the catheter is not secured properly, or if irritation causes the patient to pull on the device itself or the connecting tube, the catheter may migrate from its intended point of fixation. Any movement-induced trauma and inflammation can predispose the patient to infection and lead to tissue necrosis, blockage of urethral glands, urethral cleavage (damage to the urethral wall), and bladder irritability and spasms (Hanchett 2002). The clinical evidence to support effective catheter stabilisation as a direct contributor to minimising the risk of CAUTIs is limited. However, anecdotal evidence from the US supporting new initiatives to stabilise catheters and reduce infection rates is encouraging (Darouiche et al 2006). Providing better catheter stabilisation by the use of an approved device may address these issues.

(Ex. 1019 at 54-55.)

271. Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*” Specifically, Serany’s tray includes a “safety pin 41” and “rubber band 42,” and states that “[t]he drainage tubing 49 is attached to a bed sheet with the safety pin 41 and rubber band 42 to thereby complete the catheterization procedure.” (Ex. 1009, 3:1-5; 3:55-58.) The safety pin and rubber band thus serve as a Foley catheter securement device because the indwelling Foley catheter 48 and drainage tubing 49 are a pre-connected system so securing the drainage tubing is a means of securing the attached Foley catheter (which itself is inserted into the patient). (Ex. 1009, 3:23-26.)

275. Trays with swabs for cleaning a patient were common in the prior art. For example, Serany teaches “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.) 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.

276. 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).

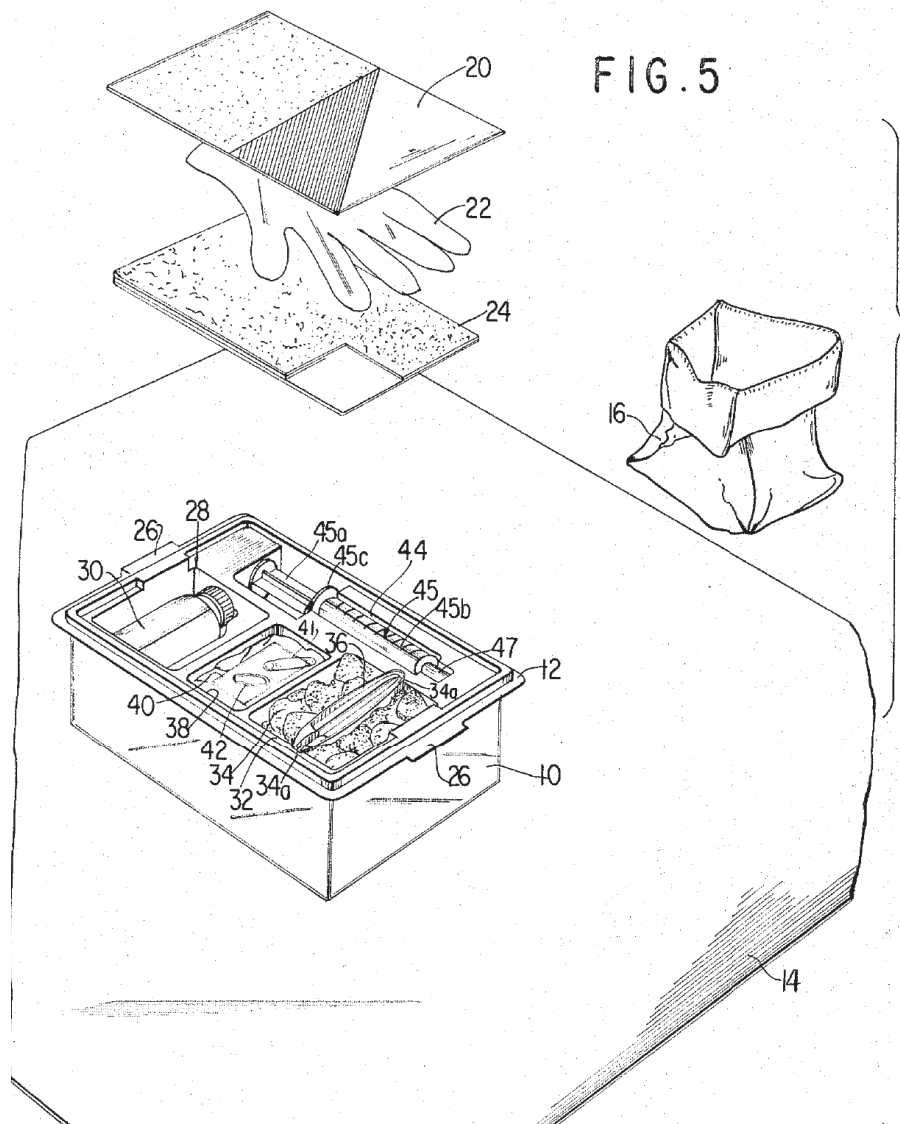
277. Accordingly, the combination of Solazzo in view of Salvadori discloses this element. The Board previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 26-27.)

278. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore renders claims 10 and 15 obvious.

3. Claims 11 and 16

279. Claims 11 and 16 recite identical additional limitations. Each claim requires “*an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.*”

280. **Underbuttocks drape.** Serany discloses “*an underbuttocks drape disposed within the outer packaging.*” Serany states: “The underpad 20, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patient. (Ex. 1009, 2:21-33; Fig. 5)



281. An underpad is the same thing as an underbuttocks drape, i.e., a drape/pad that may be placed beneath the buttocks of a patient during a urethral catheterization procedure. Illustrating the well-known nature of underpads, Disston also discloses an underpad that “is placed under the patient.” (Ex. 1008 at 2:66-70.) In view of Serany, a POSA would have been motivated to include a underbuttocks drape—a common device used in a catheterization procedure—in the catheterization

kit of Solazzo. Serany provides motivation for including an underpad by noting that it has a “plastic water-proof coating” thereby the underpad can be used to prevent or reduce the likelihood of soiling the bed during the catheterization procedure. (Ex. 1009 at 2:21-26.)

282. Furthermore, the inclusion of a underbuttocks drape in the catheterization kit of Solazzo involves the use of a known technique (provision of an underbuttocks drape) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (making Solazzo an all-in-one kit).

283. I understand the PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 27-28.)

284. **Fenestrated drape.** Serany discloses a “*fenestrated drape disposed within the outer packaging.*” Specifically, Serany states: “[a] fenestrated drape 24 folded flat underneath the gloves, is removed, unfolded, and placed in position on the patient.” (Ex. 1009, 2:30-33; Fig. 5.)

285. In view of Serany, a POSA would have been motivated to include a fenestrated drape—a common device used in a catheterization procedure—in the catheterization kit of Solazzo. Serany provides motivation for including a fenestrated drape by noting that the drape allows for the maintenance of a “sterile field.” (Ex. 1009, 2:30-33.) This also involves the use of a known technique

provision of a fenestrated drape) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (making Solazzo an all-in-one kit).

286. I understand that the Board previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 27-28.)

287. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore renders claims 11 and 16 obvious.

4. Claim 13

288. Claim 13 requires “*a Foley catheter securement device; one or more swabsticks; a specimen jar; and an outer packaging disposed about the single layer tray.*”

289. For the reasons in claim 10, Solazzo in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

290. For the reasons in claim 10, Solazzo in view of Salvadori discloses “*one or more swabsticks disposed within the single layer tray.*”

291. For the reasons in claim 6, Solazzo in view of Salvadori discloses “*a specimen jar disposed within the single layer tray.*”

292. For the reasons in claim 2, Solazzo in view of Serany discloses “*an outer packaging disposed about the single layer tray.*”

293. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore renders claims 13 obvious.

5. Claim 18

294. Claim 18 requires “*one or more swabsticks disposed within the single layer tray; a Foley catheter securement device disposed within the single layer tray; and a specimen jar disposed within the single layer tray.*”

295. For the reasons in claim 10, Solazzo in view of Salvadori discloses “*one or more swabsticks disposed within the single layer tray.*”

296. For the reasons in claim 10, Solazzo in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

297. For the reasons in claim 6, Solazzo in view of Salvadori discloses “*a specimen jar disposed within the single layer tray.*”

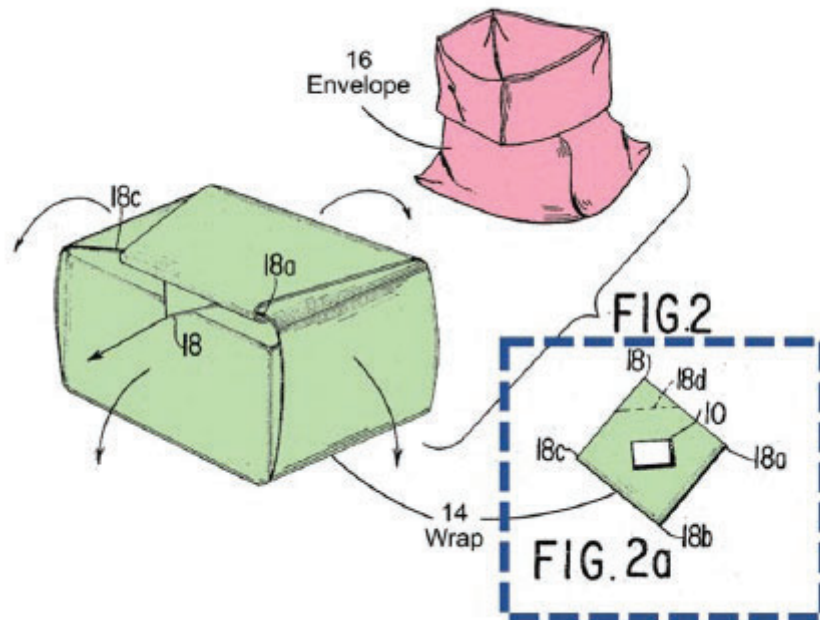
298. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore renders claims 18 obvious.

6. Claim 19

299. Solazzo in view of Serany discloses “*one or more layers of wrap material enclosing the single layer tray within one or more folds of the one or more layers of wrap material and an outer packaging disposed about the one or more folds of the one or more layers of wrap material.*”

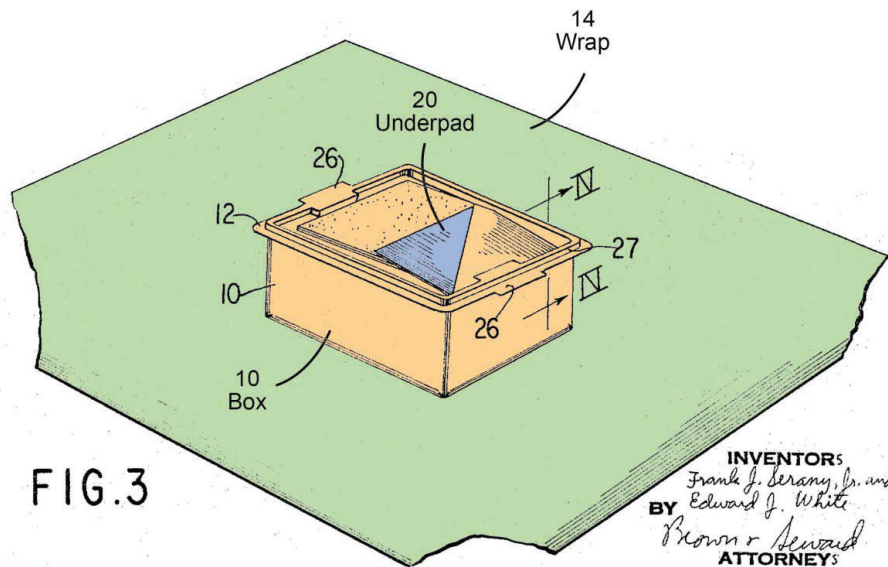
300. For the reasons at claim 2, Solazzo in view of Serany discloses the other portion of claim 19, “*an outer packaging,*” which as explained below would be “*disposed about the one or more folds of the one or more layers of wrap material.*”

301. Serany discloses a Foley catheter tray with “*at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.*” Specifically, Serany discloses a Foley catheter tray that is “enclosed within a wrap 14.” (Ex. 1009, 1:60-63.) Serany also discloses the folding one or more layers of wrap around its tray: “FIG. 2a is a plane view, on a reduced scale, of the box and wrap before the latter is folded around the former.” (Ex. 1009 at 1:48-49; Fig. 2a.) This is shown in annotated Figures 2 and 2a below:



302. Annotated Figure 2 above shows the tray enclosed within one or more folds of the at least one layer of wrap material 14 in green. Serany states “a sterile wrap [is] folded about said box and adapted to be unfolded to provide a sterile field as said components are removed from the package and used.” (Ex. 1009 at 4:49-51.)

303. Figure 3 (annotated) shows wrap 14 when unfolded:



304. The wrap of Serany ensures that “components are maintained sterile until the package is opened” and when the wrap 14 is unfolded about the tray, a “sterile field may be maintained as the components are removed from the package and used.” (Ex. 1009 at 1:13-16, 2:1-20.)

305. Serany and Solazzo are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. The wrap 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. The resulting combination would be utterly predictable.

306. It would have been obvious to a person of ordinary skill in the art to add the wrap of Serany to the catheterization tray of Solazzo. A POSA would

understand that the tray of Solazzo needs to be packaged for shipping/sale in order to (1) to hold the components in place within the compartment of the tray; (2) to prevent damage to the components, and (3) preserve the sterility of the components in the tray. Serany provides motivation to use a CSR wrap as the packaging of Solazzo because it teaches that the CSR wrap preserves the sterility of the components both before the package is opened and after the package is opened with a wrap. (Ex. 1009 at 1:13-16.) This applies a known technique (packing a medical device kit in a sterile wrap) to a known device (a Foley catheter kit) to yield predictable results (maintaining the sterility of the components within).

307. Additionally, as taught by Serany, a CSR wrap has advantages over alternative packaging methods because it can be unfolded about the tray to provide a sterile field around the tray as taught by Serany. This is beneficial in case an item from the tray were dropped onto this sterile field. When Solazzo is provided with a sterile wrap, the kit necessarily discloses the method step of “unfolding one or more layers of wrap” because the wrap must be unfolded to access the components within the tray. (Ex. 1009 at 4:49-52.)

308. A POSA would further have been motivated to combine the packaging solution taught by Serany with the tray of Solazzo because it involves applying a known technique (enclosing a tray with a wrap as shown by Serany) to a known device (a Foley catheter tray as shown by Solazzo) ready for improvement to yield

predictable results (allowing the tray of Solazzo to be shipped with sterile components and allowing for the creation of a sterile field).

309. I understand that the Board previously found substantively identical claim limitations obvious in view of the same prior art. (Ex. 1015 at 15-20.)

310. Solazzo in view of Serany, Disston, Imai, and Salvadori therefore render claims 19 obvious.

C. Ground 3: Obviousness Over Numata, Serany, and Disston

1. Independent Claim 1

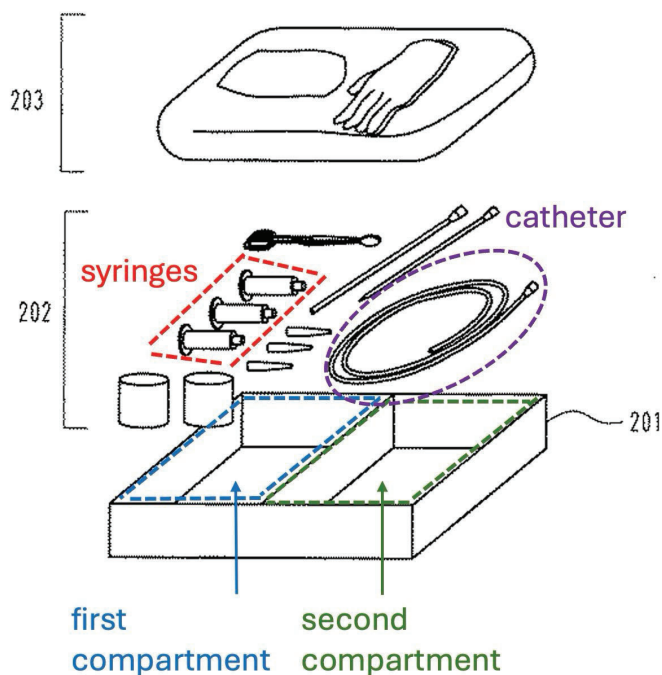
(a) Limitations 1[p] and 1[a]

311. Numata discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*”

312. 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.

313. Numata thus discloses “a single layer tray,” and the tray has multiple compartments as shown in annotated Figure 4 below:

(FIG. 4)



(Ex. 1007 at Fig. 4; ¶ 0003.)

314. 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.

315. 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.

316. Accordingly, Numata discloses this claim element.

(b) Limitation 1[b]

317. Numata discloses: “*a first syringe and a second syringe disposed within the first compartment.*” For the reasons at limitation 1[a], Numata discloses a first and a second syringe disposed within the first compartment. (Ex. 1007, Fig. 4; ¶ 0031.)

(c) Limitation 1[c]

318. Numata in view of Serany and Disston discloses “*the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*”

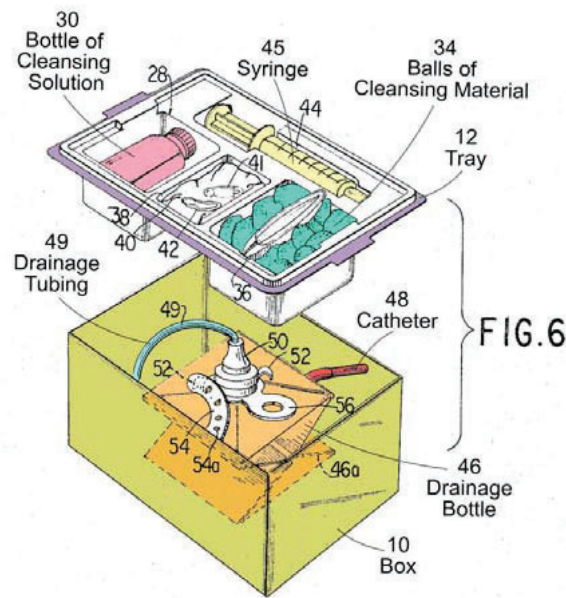
319. For the reasons at limitation 1[a], Numata discloses a medical assembly (a catheter) in a second compartment. (Ex. 1007, Fig. 4; ¶ 0031.) As discussed below, Serany and Disston disclose “*the medical assembly comprises a coiled tubing*

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.

320. 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.)

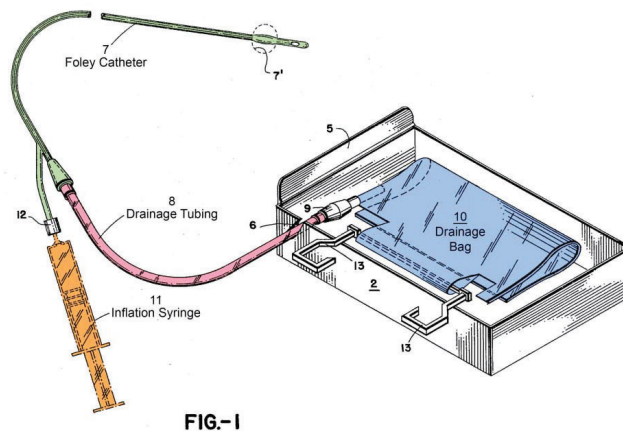
321. A closed-system Foley catheter (i.e., a Foley catheter pre-attached to a drainage bag) is a medical product that is sold sealed within packaging material in a sterilized state. Serany discloses a sterilized medical device kit were “[e]verything

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.) Serany notes that “[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 3:32-35.)



322. 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.

323. 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.

324. 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.) 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).

325. 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 ’347 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).)

326. 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.”

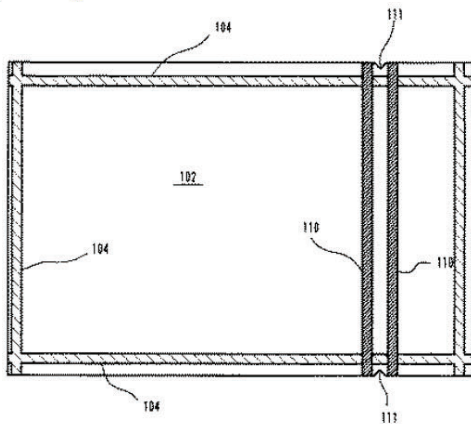
327. Third, a POSA would have been motivated to add Foley catheter equipment (such as a catheter attached to fluid bag) to the kit of Numata because several pieces of equipment stored in the kit Numata, such as syringes, gloves, cotton balls and forceps, and drapes were also commonly included in Foley 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.

328. 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

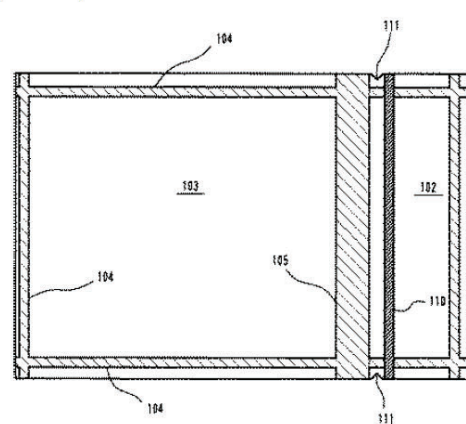
the packaging invention of Numata. Numata notes that “disposable medical instruments” are employed “to reduce the risk of nosocomial infections.” (Ex. 1007 ¶ 0002.) Specifically, Numata’s invention is designed to eliminate or reduce the risk of contamination via the outside of the outer packaging.

329. 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)

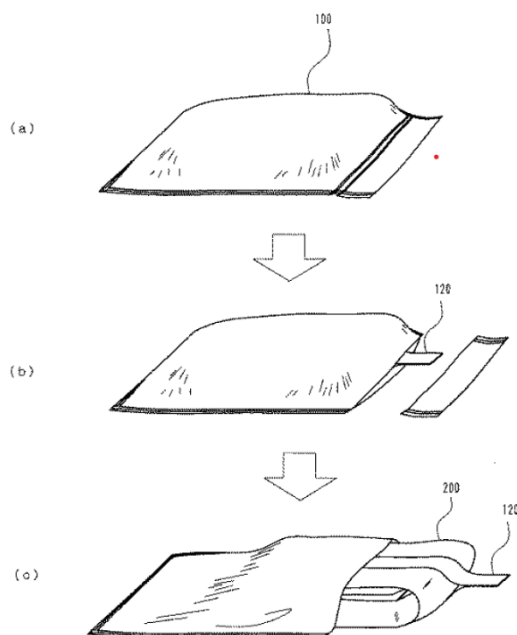


(FIG. 3)



330. 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.)

331. 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.

332. 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.)

333. 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.)

334. 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).

335. 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 '347 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).

336. 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.

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

(d) Limitation 1[d]

338. Solazzo in view of Serany and Disston discloses “*wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water.*”

339. For the reasons discussed at limitation 1[b], Numata discloses a first and second syringe. (Ex. 1009, Fig. 4, ¶ 0031.) For the reasons discussed at limitation 1[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.

340. A POSA would have been motivated to fill one 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.

341. A POSA would have also been motivated to fill another 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, 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, Beddow, and Rauschenberger also provide lubricant in their urethral catheter trays. (Ex. 1005, 4:15-25; Ex. 1010 at 3:11-16; 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.)

342. 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 pouch as taught

by Serany) for another known type of container (a syringe as taught by Numata) to produce predictable results.

343. 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. 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.

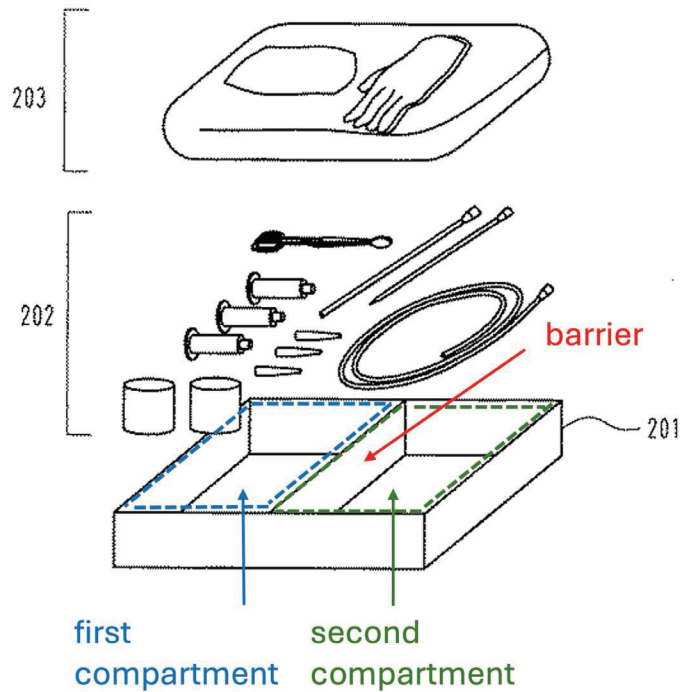
344. Accordingly, Numata in view of Serany and Disston discloses this claim element.

(e) Limitation 1[e]

345. Numata discloses “*wherein the first compartment and the second compartment are adjacent and separated by a barrier.*”

346. As shown in annotated Figure 4 below, Numata discloses the first compartment and the second compartment are adjacent and separated by a barrier:

(FIG. 4)



347. The internal divider wall shown in Figure 4 is a barrier because it is a structure that prevents or blocks movement from or access between one compartment to another. Specifically, a POSA would understand that the divider wall is a barrier as it prevents the movement of equipment from one compartment to another (e.g., it keeps the catheter separate from the syringes).

348. Accordingly, Numata discloses this claim element.

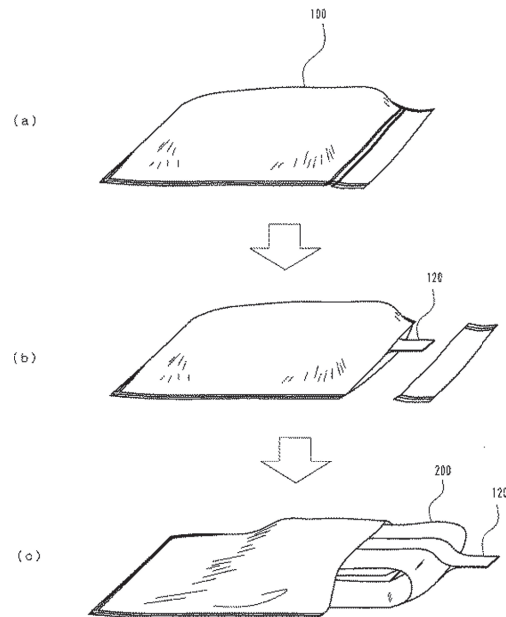
349. Numata in view of Serany and Disston therefore renders claim 1 obvious.

2. Claim 2

350. Numata discloses “*further comprising an outer packaging disposed about the single layer tray.*”

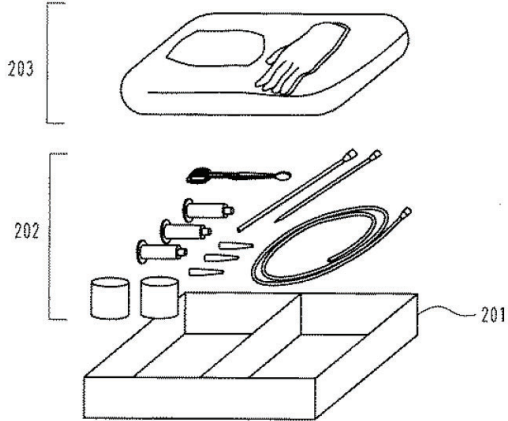
351. Numata discloses a “packaging bag 100 for sealing the medical product 200” as shown in Figure 7. (Ex. 1007 at Abstract; ¶¶ 0022-25, Fig. 7.)

(FIG. 7)

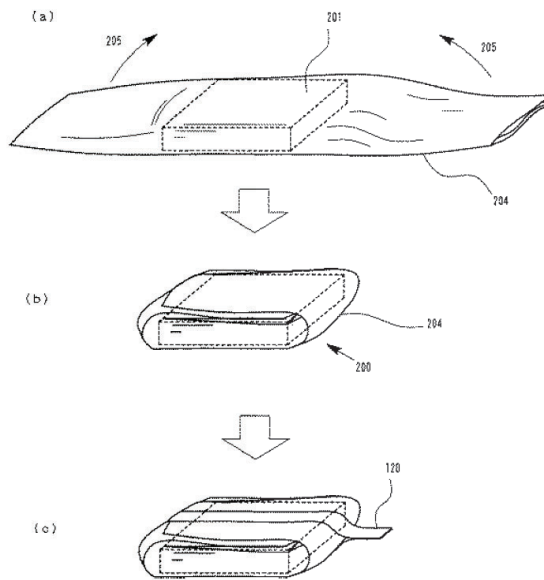


352. As shown in Figures 4 and 5 below, the outer packaging 100 is disposed about the single layer tray 201, which is wrapped in cloth 204 before being sealed by the outer packaging 100.

(FIG. 4)



(FIG. 5)



(Ex. 1007 at Abstract, Figs. 5-6.)

353. Accordingly Numata discloses this claim element. Numata in view of Serany and Disston therefore renders claim 2 obvious.

3. Claim 5

354. For the reasons at limitation 1[d], Numata in view of Serany discloses “*wherein the water is sterile.*” Numata in view of Serany and Disston therefore renders claim 5 obvious.

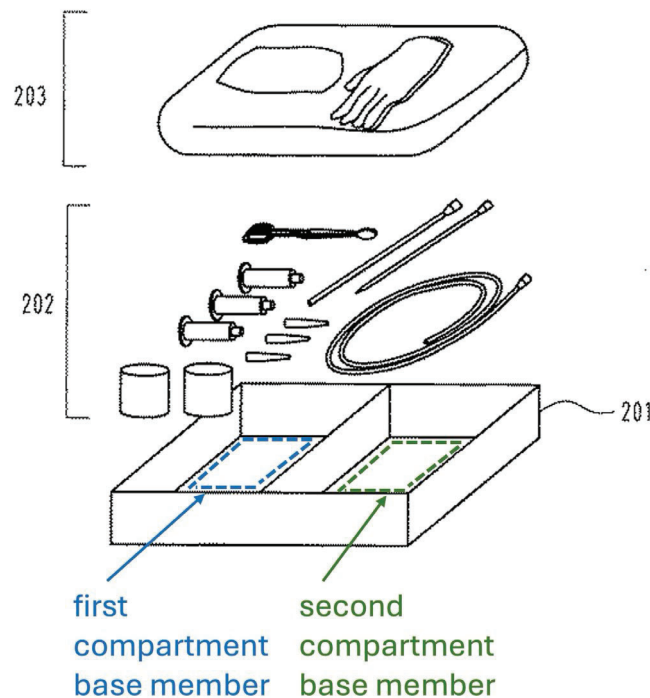
4. Claim 7

355. Numata discloses “*wherein the first compartment is bounded by a first base member and the second compartment is bounded by a second base member.*”

356. As discussed at Ground 1, claim 7, a compartment base member as that term is used in the '347 patent is the bottom surface of the compartment.

357. As shown in annotated Figure 4 below, Numata discloses the “*first compartment is bounded by a first base member and the second compartment is bounded by a second base member*” as each compartment of Numata is bounded by the bottom surface of the tray:

(FIG. 4)



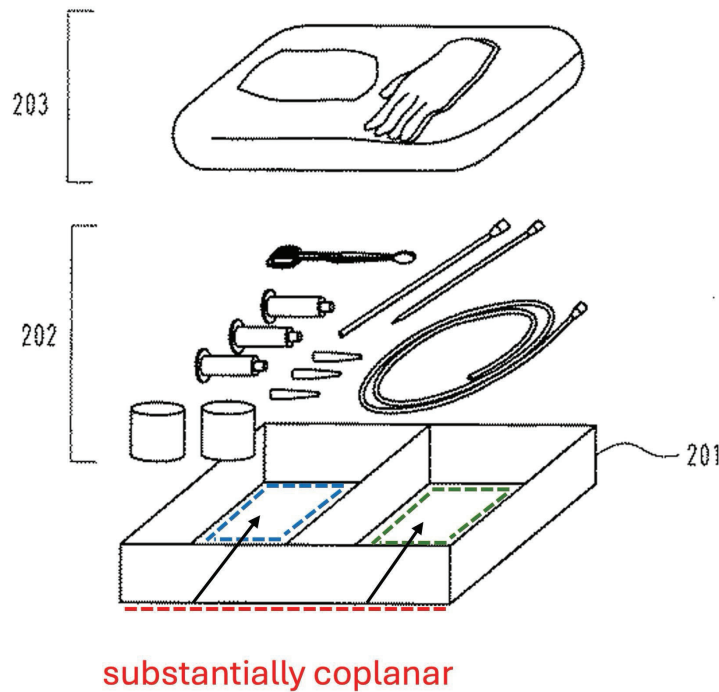
(Ex. 1007 at Fig. 4.)

5. Claim 8

358. Numata discloses “*wherein a portion of the first base member and another portion of the second base member are substantially coplanar.*”

359. As shown in annotated Figure 4, Numata discloses a tray with a flat bottom surface with the base member of both compartments lying in the same plane, and thus the base members are substantially coplanar.

(FIG. 4)



360. Numata in view of Serany and Disston therefore renders claim 8 obvious.

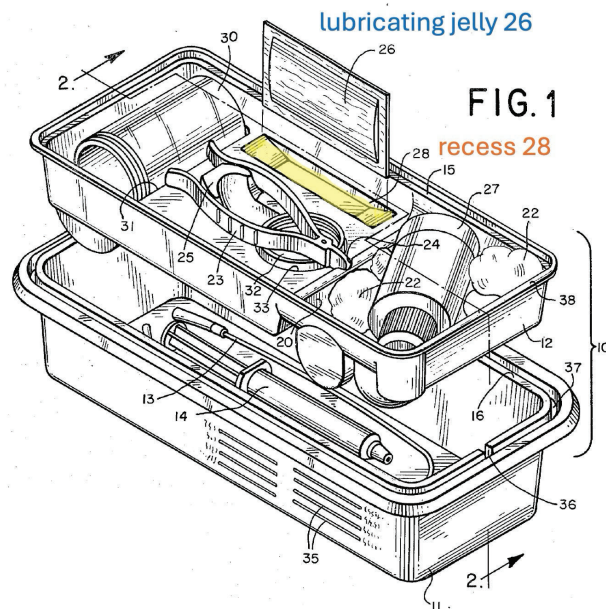
D. Ground 4: Obviousness Over Numata, Serany, Disston and Beddow

1. Claim 3

361. Numata in view of Beddow discloses “*the first compartment defining a lubricating jelly application compartment.*” As discussed at limitation 1[e] above, Numata discloses multiple syringes in a first 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.

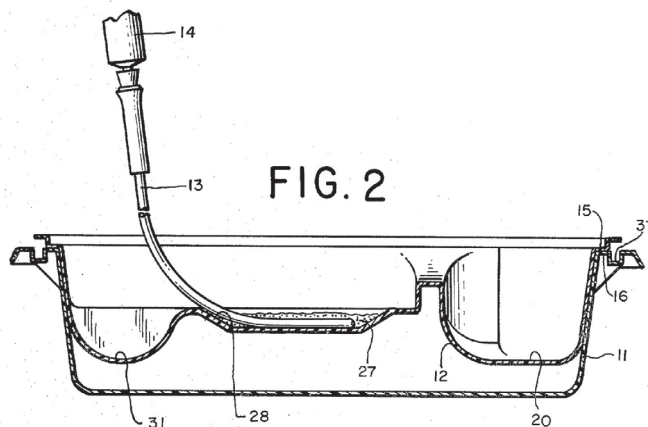
362. It was known in the art to lubricate the catheter in the compartment where the lubricant is stored in view of Beddow. Specifically, Beddow teaches using the compartment that stores the lubricant as a lubricating jelly application compartment to receive lubricating jelly: “To provide for lubrication 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.)

363. 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.



364. 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.)



365. In view of Beddow, a POSA would have been motivated to use the first compartment of Numata as a lubricating jelly application compartment because the first compartment would also store the lubricant for the reasons at limitations 1[b] and 1[d]. 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.

366. A POSA would also have recognized that 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.

367. *First*, as discussed at limitation 1[c], 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 ’347 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.

368. *Second*, Numata's second compartment (a lubricating jelly application compartment) is easily accessible because the tray has an open top. (Ex. 1007 ¶¶ 0005.) Additionally, the compartment is not particularly deep (likely two to three inches as discussed above). The tray is also a "single tray" (which Numata states helps "prevent usage errors and preparation errors") and the lubrication compartment is thus adjacent to the compartment that stores the Foley catheter. *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.)

369. 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.

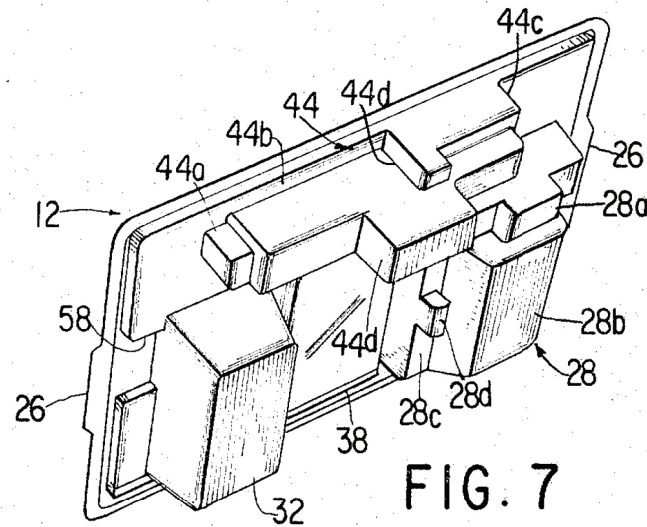
370. To the extent this claim is deemed to require a specific structure that is not otherwise disclosed by Numata, it would have been obvious to add contouring such as a depression to the first compartment of Numata in view of Serany to accommodate the lubricant and water syringes to prevent movement during shipping. A POSA would understand that a lubricant and water syringe were each approximately six inches in length in 2009, which I know based on my work with

Foley catheter kits in that timeframe and this has also been confirmed by Dr. Yun. (See also Ex. 2020 (showing a water and lubricant syringe that are approximately the same length).) This depression would thus 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).

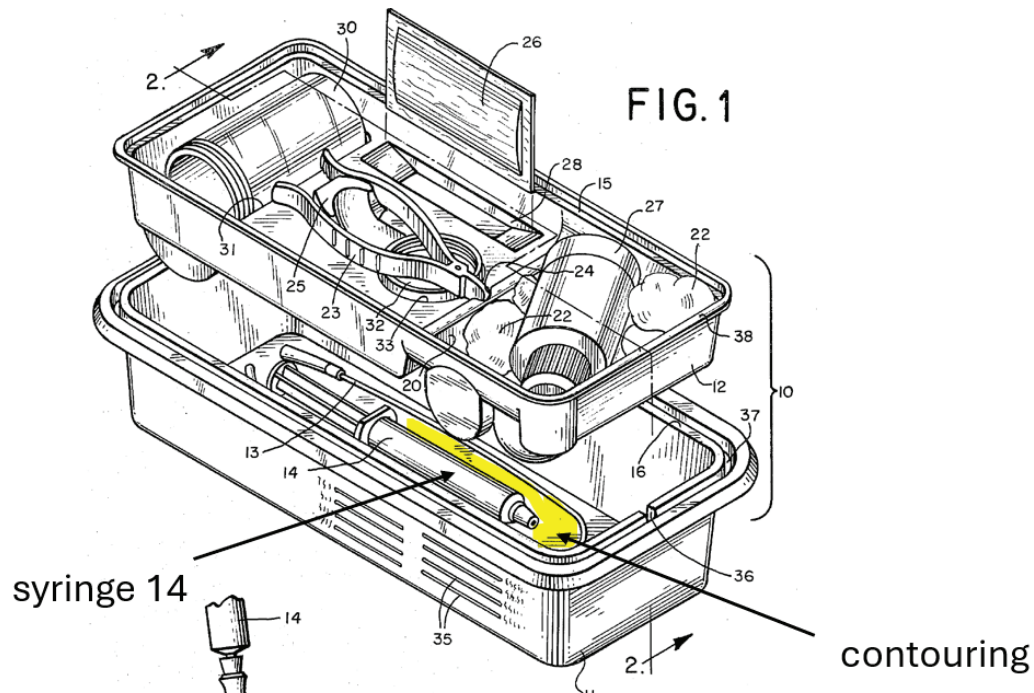
371. Because the tray of Numata does not provide any specific mechanism to hold the syringes in place within the first compartment of tray 201, the syringes could move during shipment of the tray. This could damage the syringes or the other equipment disposed within the first compartment and a POSA would thus have been motivated to modify the tray of Numata to hold the syringes in place.

372. 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:



373. Beddow also teaches a tray that includes contouring for holding syringe 14 as shown in Figure 1 below:

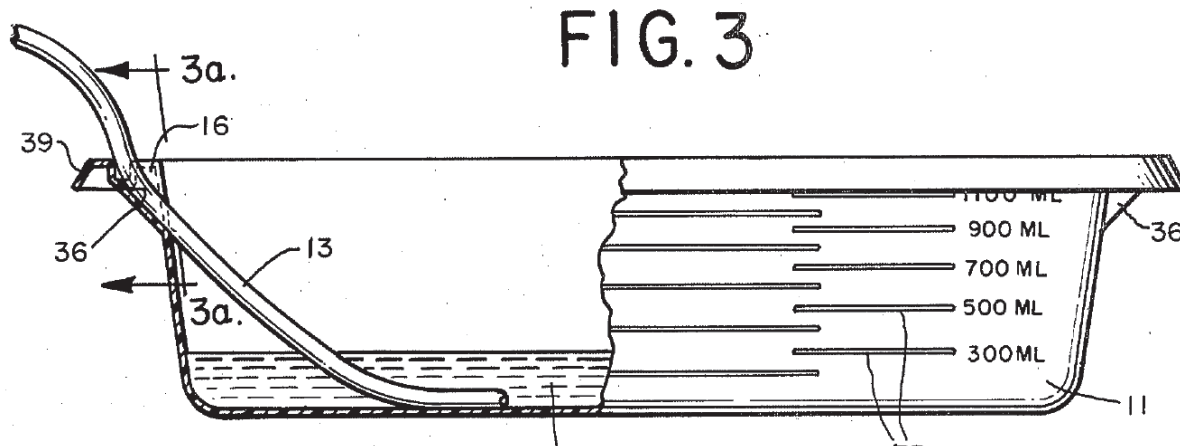


(Ex. 1010 at Fig. 1, 2:46-52, 4:14-17.)

374. 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.)

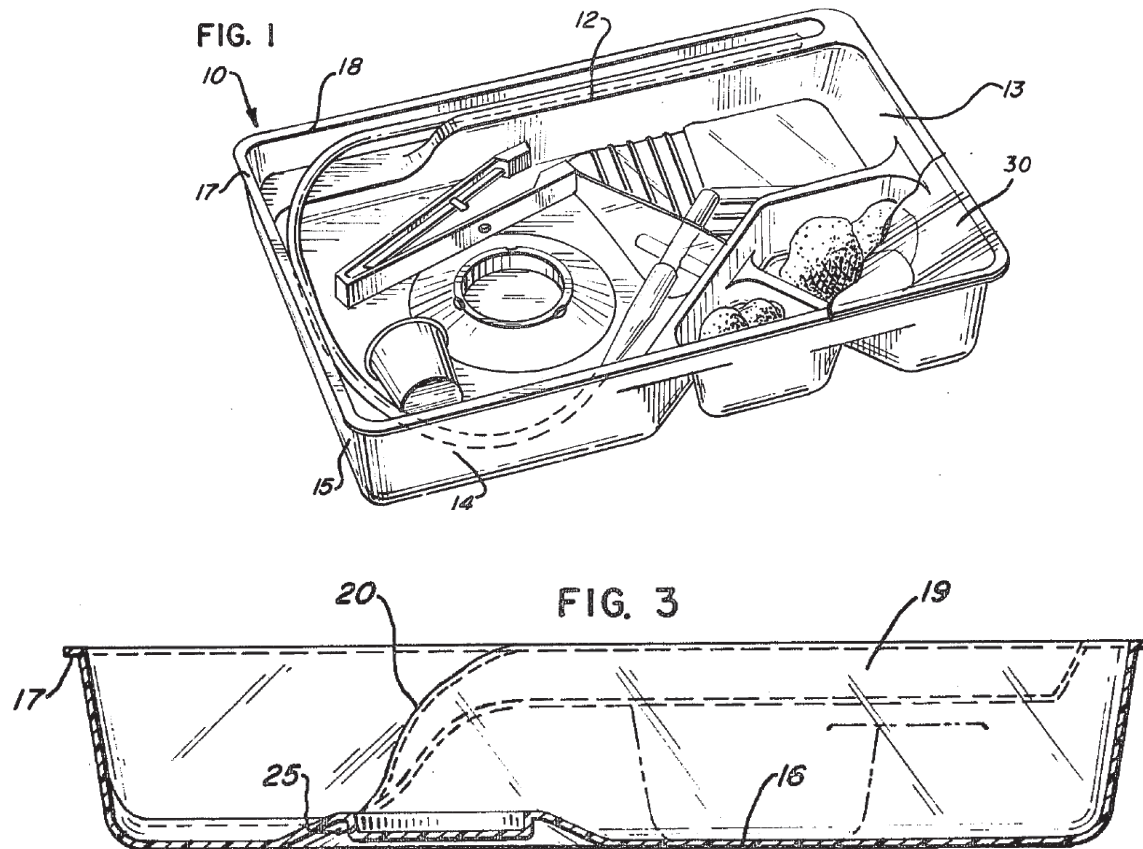
375. A POSA would understand that such contouring could easily be done when manufacturing the tray of Numata made using thermoforming or injection molding techniques, either of which could be used to manufacture Numata's tray for the reasons at limitation 17[a]. For example, Beddow discloses a thermoformed tray and Rauschenberger discloses an injection molded tray for the reasons at limitation 17[a].

376. 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 (below), but includes contouring to hold a syringe (as shown in Figure 1 (above)) within a raised compartment of the tray:



377. 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 stacked in this compartment for the reasons at claim 14[f] and [g] below.

378. 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.)



379. 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.

380. By adding contouring to accommodate the syringes, this would form a lubrication channel within the first compartment by allowing the lubricant to pool in a contoured area that is around the same length as the five inches of the catheter that I understand from Dr. Yun ideally should be lubricated. Indeed, 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.)



381. Numata in view of Serany, Disston, and Beddow therefore renders claim 3 obvious.

2. Claim 4

382. Claim 4 requires “*the lubricating jelly application compartment configured to receive lubricating jelly from the one of the first syringe or the second syringe to lubricate at least some of the Foley catheter when the Foley catheter is passed into the first compartment.*”

383. For the reasons at claim 3, Numata in view of Beddow discloses “*the lubricating jelly application compartment configured to receive lubricating jelly from the one of the first syringe or the second syringe to lubricate at least some of the Foley catheter when the Foley catheter is passed into the first compartment.*” Specifically, as discussed at claim 3, the first compartment of Numata would be modified in accordance with Beddow to receive lubricating jelly from the lubricant

syringe to lubricate at least some of the Foley catheter (e.g., at least the tip) when the Foley catheter is passed into the first compartment. A POSA would understand that the Foley catheter can be passed from the second compartment of Numata to the first compartment by passing it over the internal wall because the tray has an open top and could be made to have a relatively minor depth (2 to 3 inches as discussed at limitation 1[c]). (Ex. 1007 at Fig. 4.) Passing the catheter over an internal wall is a trivial operation as compared to Beddow where the catheter is passed from tray to tray. With respect to Numata, “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.) Allowing the catheter to be lubricated within the sterile surface of the tray of Numata without needing to remove it from the tray is one such advantage of packing the equipment “together in a single tray.” (See also Ex. 1021 at 1:8-2:42 (noting that “prior art devices” required lubricating the catheter on a CSR wrap and disclosing a single layer tray where the catheter can be lubricated in one of the compartments of the tray).

384. Accordingly, Numata in view of Beddow also discloses this claim element. Numata in view of Serany, Disston, and Beddow therefore renders claim 4 obvious.

E. Ground 5: Obviousness Over Numata, Serany, Disston, and Salvadori

1. Claim 6

385. Claim 6 requires “a specimen jar disposed within the single layer tray.”

When customizing the kit of Numata to include urinary catheter equipment For the reasons in claim 1[c], it would have been obvious to add a specimen jar to the kit of Numata.

386. Salvadori is a urethral catheter kit that discloses “specimen bottle 68,” which a POSA would understand is a specimen jar as “specimen jar” and “specimen bottle” are interchangeable as they both refer to small, cylindrical containers that are used to collect a urine sample. (Ex. 1013, 1:12-16; 3:8; Figure 1.)

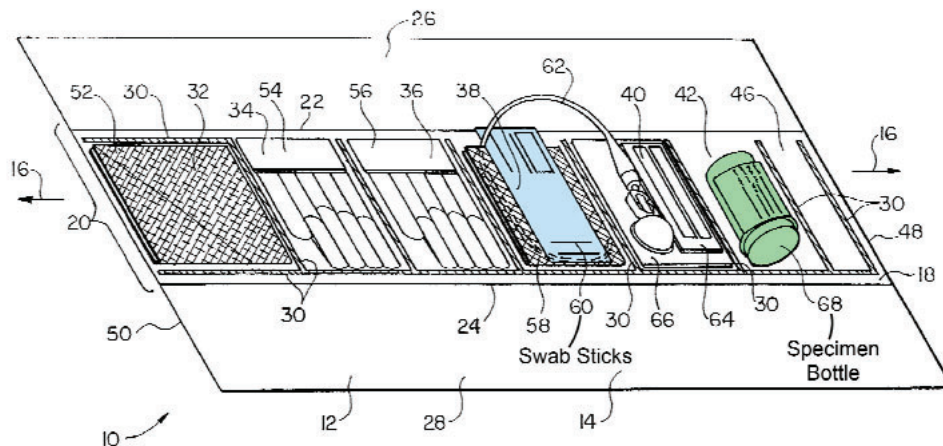


FIG. 1

387. Specimen jars were common in prior art catheter trays (as in Salvadori, Beddow, and Rauschenberger). (Ex. 1010, 1:21-25; Ex. 1013, 3:8; Ex. 1014, 1:21-

25.) They are used to take a specimen of urine from a patient “if there is a clinical need to take a catheter specimen or urine.” (Ex. 1019, 51.)

388. In view of Salvadori, a POSA would have been motivated to include a specimen jar in the catheterization kit of Numata to allow a practitioner to take a urine sample when the clinical need arises, e.g., to run an assay of the urine to determine if the patient has a urinary tract infection.

389. This involves the use of a known technique (provision of a specimen jar) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (making Numata an all-in-one Foley catheter kit by including a common piece of equipment in the kit).

390. Accordingly, the combination of Numata in view of Salvadori discloses this element. Numata in view of Serany, Disston, and Salvadori, therefore renders claim 6 obvious.

2. Claim 10

391. Claims 10 requires “*an outer packaging disposed about the single layer tray; a Foley catheter securement device disposed within the single layer tray; and one or more swabsticks disposed within the single layer tray.*”

392. **Outer Packaging.** For the reasons stated for claim 2, Numata discloses “*an outer packaging disposed about the single layer tray.*”

393. **Catheter Securement Device.** Numata in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

394. When customizing the kit of Numata to include urinary catheter equipment for the reasons at limitation 1[c], it would have been obvious to add a Foley catheter securement device to the kit of Numata as it was known to secure the catheter to the bed to minimize movement of the indwelling catheter, which could reduce the risk of infection. Nursing Standard notes (citing to 2002 and 2006 studies) that stabilizing the catheter via a catheter securement device was a known technique that could reduce infection rates:

If the catheter is not secured properly, or if irritation causes the patient to pull on the device itself or the connecting tube, the catheter may migrate from its intended point of fixation. Any movement-induced trauma and inflammation can predispose the patient to infection and lead to tissue necrosis, blockage of urethral glands, urethral cleavage (damage to the urethral wall), and bladder irritability and spasms (Hanchett 2002). The clinical evidence to support effective catheter stabilisation as a direct contributor to minimising the risk of CAUTIs is limited. However, anecdotal evidence from the US supporting new initiatives to stabilise catheters and reduce infection rates is encouraging (Darouiche et al 2006). Providing better catheter stabilisation by the use of an approved device may address these issues.

(Ex. 1019 at 54-55.)

395. Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*” Specifically, Serany’s tray includes a “safety pin 41” and

“rubber band 42,” and states that “[t]he drainage tubing 49 is attached to a bed sheet with the safety pin 41 and rubber band 42 to thereby complete the catheterization procedure.” (Ex. 1009, 3:1-5; 3:55-58.) The safety pin and rubber band thus serve as a Foley catheter securement device because the indwelling Foley catheter 48 and drainage tubing 49 are a pre-connected system so securing the drainage tubing is a means of securing the attached Foley catheter (which itself is inserted into the patient). (Ex. 1009, 3:23-26.)

396. In view of Serany, a POSA would have been motivated to include a Foley catheter securement device in the catheterization kit of Numata to allow for the Foley catheter to be properly secured when inserted. Furthermore, the inclusion of a Foley catheter securement device in the catheterization kit of Numata involves the use of a known technique (application of a securement device during a catheterization procedure) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (providing a securement device in the tray so that the practitioner can secure the catheter after it inserted in the patient).

397. Accordingly, the combination of Numata in view of Serany discloses this element.

398. **Swabsticks.** Numata in view of Salvadori discloses “*one or more swabsticks disposed within the single layer tray.*”

399. When customizing the kit of Numata to include urinary catheter equipment for the reasons at limitation 1[c], it would have been obvious to add swabsticks to the kit of Numata because it was well-known to provide equipment for cleaning the patient's genitals prior to catheter insertion in urinary catheter kits.

400. 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., presaturated.

401. 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 kits. (Ex. 1007 ¶ 31; Fig. 4.)

402. Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (Ex. 1009, 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.

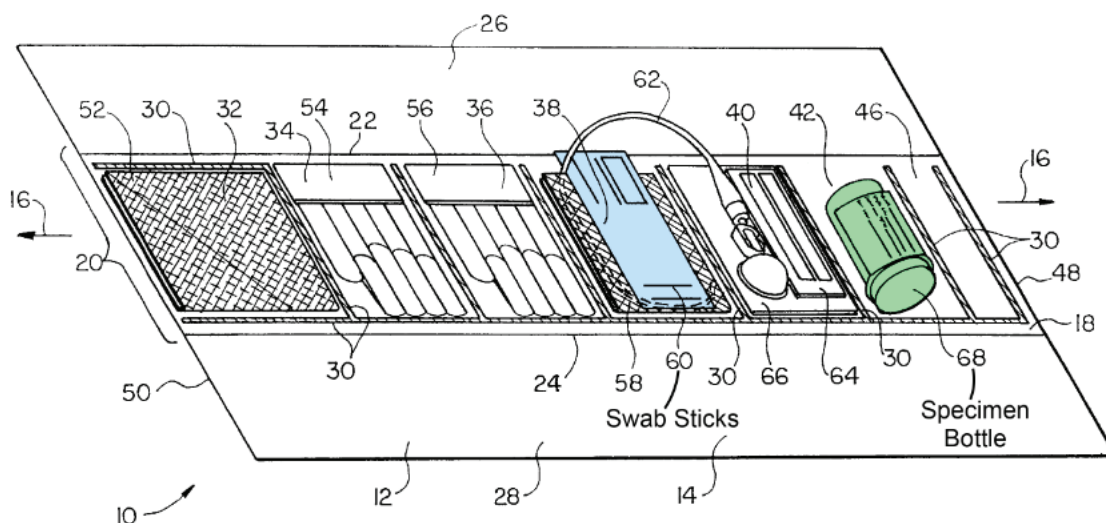


FIG. 1

403. 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.

404. 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.

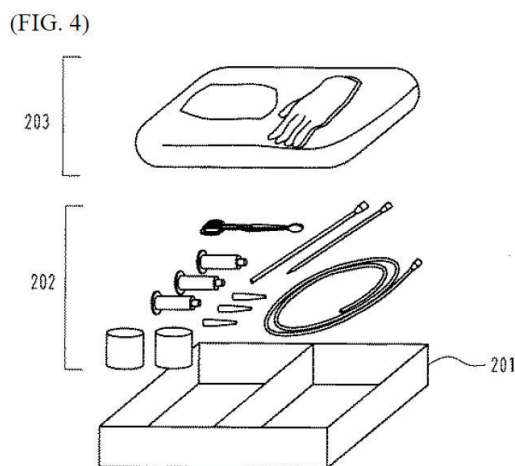
405. A POSA would have further been motivated to include swabsticks over the other available options because a swabstick is easier to manipulate than forceps. Specifically, a clinician could inadvertently drop a ball or pad if they do not maintain constant pressure with the forceps to grasp the ball/pad,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

406. Accordingly, the combination of Numata in view of Salvadori discloses this claim element. Numata in view of Serany, Disston, and Salvadori therefore render claim 10 obvious.

3. Claim 11

407. Claim 11 requires “*an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.*” Numata in view of Serany disclose “*an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.*”

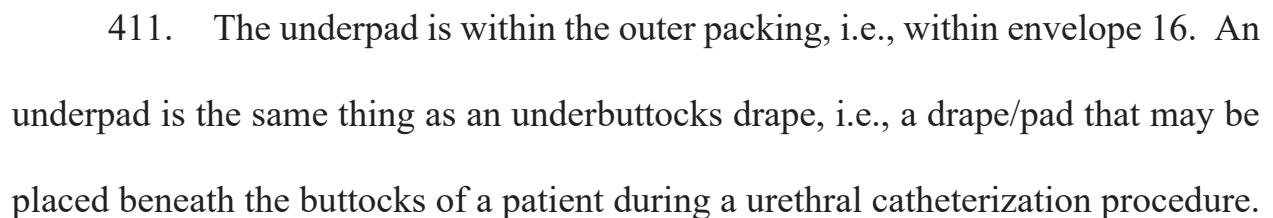
408. Numata disclose includes “a drape (nonwoven fabric used in place of sheets” within the outer packaging of Numata (i.e., within packaging bag 100 which is placed around items 203 at shown in Figures 4 and 6-7). (Ex. 1007 ¶¶ 0031-33; Fig.4.) Specifically, the drape is placed with other medical instruments 203 in Figure 4.



(Ex. 1007 ¶¶ 0031-33; Fig.4.)

409. When customizing the kit of Numata for a urinary catheterization procedure for the reasons at claim 1[c], it would have been obvious to substitute Numata’s “drape” with an “underbuttocks drape” and a “fenestrated drape,” which

410. **Underbuttocks drape.** Serany discloses “*an underbuttocks drape disposed within the outer packaging.*” Serany states: “The underpad 20, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patent. (Ex. 1009, 2:21-33; Fig. 5)



Illustrating the well-known nature of underpads, Disston also discloses an underpad that “is placed under the patient.” (Ex. 1008 at 2:66-70.) In view of Serany, a POSA would have been motivated to include a underbuttocks drape—a common device used in a catheterization procedure—in the catheterization kit of Solazzo. Serany provides motivation for including an underpad by noting that it has a “plastic waterproof coating” thereby the underpad can be used to prevent or reduce the likelihood of soiling the bed during the catheterization procedure. (Ex. 1009 at 2:21-26.) This also involves the use of a known technique provision of a underbuttocks drape) to a known device (a catheter kit) ready for improvement to yield predictable results (making Numata an all-in-one kit).

412. **Fenestrated drape.** Serany discloses a “*fenestrated drape disposed within the outer packaging.*” Specifically, Serany states: “[a] fenestrated drape 24 folded flat underneath the gloves, is removed, unfolded, and placed in position on the patient.” (Ex. 1009 at 2:30-33; Fig. 5.)

413. In view of Serany, a POSA would have been motivated to include an underbuttocks drape and a fenestrated drape—common drapes used in a urinary catheterization procedure—in the catheterization kit of Numata. Serany provides motivation for including a fenestrated drape by noting that the drape allows for the maintenance of a “sterile field.” (Ex. 1009 at 2:30-33.) This also involves the use of a known technique provision of a fenestrated drape) to a known device (a Foley

catheter kit) ready for improvement to yield predictable results (making Numata an all-in-one kit).

414. Accordingly, the combination of Numata in view of Serany discloses this claim element. Numata in view of Serany, Disston, and Salvadori therefore render claim 11 obvious.

4. Claim 13

415. Claim 13 requires “*a Foley catheter securement device; one or more swabsticks; a specimen jar; and an outer packaging disposed about the single layer tray.*”

416. For the reasons in claim 10, Numata in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

417. For the reasons in claim 10, Numata in view of Salvadori discloses “*one or more swabsticks.*”

418. For the reasons in claims 6, Numata in view of Salvadori discloses “*a specimen jar.*”

419. For the reasons in claim 2, Numata discloses “*an outer packaging disposed about the single layer tray.*”

420. Numata in view of Serany, Disston, and Salvadori therefore render claim 13 obvious.

F. Ground 6: Obviousness Over Numata, Serany, Disston, and Imai

1. Independent Claim 14

(a) Limitation 14[p] and 14[a]

421. For the reasons in limitations 1[p] and [a], Numata discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*”

(b) Limitation 14[b]

422. For the reasons in limitation 1[b], Numata discloses “*a first syringe and a second syringe disposed within the first compartment.*”

(c) Limitation 14[c]

423. For the reasons in limitation 1[c], Numata, Serany and Disston disclose “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*”

(d) Limitation 14[d]

424. For the reasons in limitation 1[d], Numata and Serany discloses “*wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water.*”

(e) Limitation 14[e]

425. For the reasons in limitation 1[e], Numata discloses “*the first compartment and the second compartment are adjacent and separated by a barrier.*”

(f) Limitation 14[f]

426. Limitation 14[f] requires “*the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure.*” Numata in view of Serany discloses “*the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure.*”

427. 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 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,” “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.)

428. 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.)

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

430. For the reasons in limitation 1[d], 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 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 discussed at limitation 14[g]). Alternatively, this order could be reversed if a test balloon step is performed as that requires using the water syringe first.

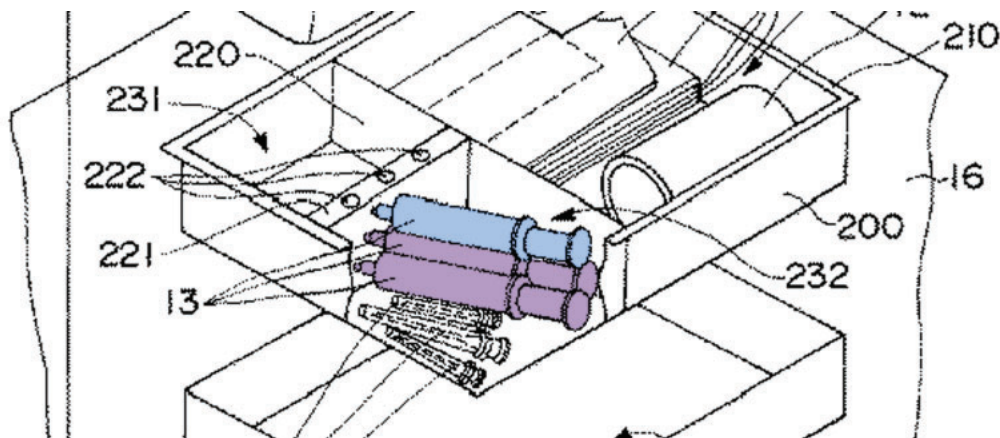
431. A POSA would have been motivated to arrange the syringes in their order of use in the kit of Numata. Serany provides such motivation by teaching components that are “arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” (Ex. 1009 at 1:9-35.) Arranging items in their 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 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”).

(g) Limitation 14[g]

432. Limitation 14[g] requires “the first compartment supports the first syringe and the second syringe at different heights.”

433. As discussed at limitation 14[f], it would have been obvious to arrange syringes in their order of use. It would have been obvious to try arranging them at different heights given the finite number of options available to arrange the syringes (by height versus left-to-right). For example, Imai discloses stacking syringes in a catheter tray at different heights, which was a well-known way to arrange equipment,

including syringes, within a tray. Thus, a POSA would have understood that when placing multiple syringes in the second compartment of Numata in their order of use, the syringes could be stacked on top of each other in view of Imai:



(Ex. 1012 ¶ 0014; 0031; Fig. 1.) For example, as discussed at limitation 14[f], the syringes could be arranged with the lubricant syringe on the top (because it is used first) and the inflation and irrigation syringes below the lubricant syringe (as those are used later in the procedure).

434. Numata and Imai are also analogous references as both are catheter kits for storing similar medical device equipment, including a catheter and multiple syringes. (Ex. 1008 at Fig. 1, ¶0033; Ex. 1012 at Fig. 1; ¶ 0078.) Thus, there would have been a reasonable expectation of success in combining these references.

435. A POSA would have been motivated to combine the packaging solution taught by Imai with the tray of Numata because it involves applying a known technique (stacking syringes at different heights) to a known device (a catheter tray as shown by Numata) ready for improvement to yield predictable results (ordering

components in a manner that is convenient for the user and to save space within the tray). Also, it would have been obvious to try stacking the syringe at different heights consistent with their order of use because there were a finite number of identified, predictable solutions (i.e., placing the syringes at the same height or stacking them at different heights) with a reasonable expectation of success (as stacking items within a tray was a well-known solution as shown by Imai).

436. Accordingly, Numata in view of Imai discloses this claim element. Numata in view of Serany, Disston, and Imai therefore renders claim 14 obvious.

G. Ground 7: Obviousness Over Numata, Serany, Disston, Imai and Salvadori

1. Claim 15

437. Claim 15 requires “*an outer packaging disposed about the single layer tray; a Foley catheter securement device disposed within the single layer tray; and one or more swabsticks disposed within the single layer tray.*”

438. For the reasons at claim 2, Numata discloses “*an outer packaging disposed about the single layer tray.*”

439. For the reasons at claim 10, Numata in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

440. For the reasons at claim 10, Numata in view of Salvadori discloses “*one or more swabsticks disposed within the single layer tray.*”

2. Claim 16

441. Claim 16 requires “an *underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.*” For the reasons at claim 11, Numata in view of Serany discloses “an *underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging.*”

H. Ground 8: Obviousness Over Numata, Serany, Disston, Imai Salvadori, and Beddow

1. Independent Claim 17

(a) Limitations 17[p] and 17[a]

442. Claim 17 requires “*A medical procedure kit, comprising: a surface defining a single layer tray having a first compartment adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.*”

443. For the reasons at limitations 1[a] and [e], Numata discloses “*a single layer tray having a first compartment adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.*”

444. Numata discloses or renders obvious in view of Beddow “*a surface defining a single layer tray having a first compartment separated by a barrier from, a second compartment.*” I understand that the Board previously interpreted similar

claim language as requiring a single surface, i.e., that the barrier is integrally formed. Numata discloses that “tray 201 [is] **molded** from hard plastic or the like.” (*Id.* ¶ 0031 (emphasis added).)

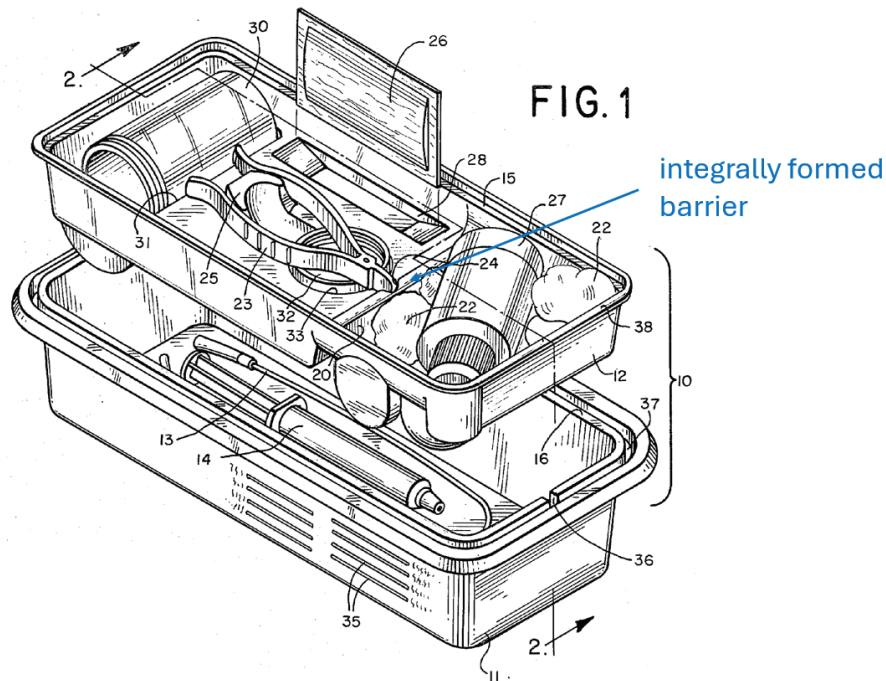
445. A POSA would have understand that a tray that is “molded” could refer to injection molding or thermoforming as both involve the use of molds. To the extent “molded” refers to one specific method of manufacturing a tray, it would have been obvious to try utilizing the other method as both injection molded and thermoforming were well-known methods for manufacturing at tray at the time of Numata’s filing, and thus there were a finite number of options to choose from when manufacturing Numata’s plastic tray with a reasonable expectation of success.⁴ A POSA would have been further understood that either method allows for the construction of a tray from a single surface with an integrally formed barrier. I note that the specification of the ’347 patent confirms that either a “thermally formed” or “injection molded” tray is appropriate for forming a “surface defining a single layer

⁴ For example, if Medline were to argue that Numata discloses an injection molded tray and that forming the wall integrally was not possible with injection molding (I disagree and the Board has previously concluded otherwise), then in view of Beddow, a POSA would have been motivated to manufacture the tray of Numata using thermoforming. This applies a known technique (forming a single level tray as a part of a single surface using thermoforming) to a known device (a catheter tray) ready for improvement to yield predictable results (strengthening the tray while utilizing a manufacturing technique that is generally known to be cheaper and faster).

tray having a first compartment separated by a barrier from, a second compartment.” (Ex. 1001 at 4:39-50.) Indeed, at the time of the invention, both thermoforming and injection molding were well-known methods for manufacturing a tray such as the tray shown in Figure 1 of Beddow, which includes multiple compartments and rounded edges. As discussed below, Beddow’s tray is formed from a single surface with multiple compartments and is “thermoformed.” (Ex. 1010 at 2:55-57; Fig. 1) Additionally, as discussed at Section IX.11, Fulbrook’s injection molded tray is also formed from a single surface with multiple compartments. (Ex. 1029 at Figs. 1-5, Abstract; 3:61-62; 5:50-53; 11:61-64.)

446. It also would have been obvious to a POSA to form the internal wall of Numata integrally with the tray. This applies a known technique (forming an internal wall integrally using known manufacturing methods) to a known device a catheter (kit) to yield predictable results (allowing for the efficient manufacture of a robust tray).

447. It was well-known when thermoforming a tray to form barriers (i.e., internal tray walls) integrally with the tray. For example, Beddow discloses “The base and tray portions may be thermoformed by conventional methods from a thin plastic material.” (Ex. 1010 at 2:55-57.) A POSA viewing Figure 1 of Beddow would understand that its divider walls are integrally formed to separate components and add structural rigidity. (Ex. 1010 at Fig. 1.)



448. With respect to thermoforming tray 201 of Numata, the tray and internal wall would almost certainly be formed from a single sheet (surface) of material. The alternative—using multiple molds to create separate components and then needing to fasten the internal wall to the tray—would add manufacturing complexity and parts resulting in a tray that is more expensive while also having potential for lower quality (added assembly steps increases risk of lower quality) and risk of leaks. Thus, when using thermoforming, a POSA would understand that the internal wall of Numata’s tray 201 would (or, at a minimum, easily could) be integrally formed with the rest of the tray.

449. It was also well-known when using injection molding to form barriers (i.e., internal tray walls) integrally with the tray. As with thermoforming, such

manufacturing techniques also have the advantage of allowing for a more durable tray while streamlining manufacturing (e.g., by using a single mold with multiple gates to avoid areas of high stress concentration in the tray.) (Ex. 1029 at 11:61-64 (noting that 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.”) I understand that Medline’s expert, Dr. Paul Sher Singh “testified that a different prior art single layer tray [Rauschenberger] that was formed by injection molding depicted a molded surface defining multiple compartments separated by a barrier.” (Ex. 1015 at 34.) I agree that a POSA would understand the tray of Rauschenberger is formed from a single contoured surface that defines the compartments of the tray, including the divider walls, and the tray could be formed from injection molding. (Ex. 1021 at Figs. 1-3; 1:50-61.) Additionally, Fulbrook is another example of single layer medical device tray that is injection molded and includes multiple compartments to store components such as syringes that is formed from a single surface. (Ex. 1029 at Figs. 1-5, Abstract; 3:61-62; 5:50-53; 11:61-64.) Thus, when using injection molded, a POSA would understand that the internal wall of Numata’s tray 201 would (or, at a minimum, easily could) be integrally formed with the rest of the tray.

450. A POSA would also have been motivated to form the internal wall integrally when using either thermoforming or injection molding because it is the

more reasonable and cost-effective solution than a separate piece for the reasons below. *First*, if the divider wall is a separate piece then multiple molds will be required for both the tray and the divider wall instead of a single mold—adding cost and complexity.⁵ Additionally, an additional manufacturing step will be required to add the divider wall to the tray. In sum, a POSA would understand that forming the divider wall separately would be a more costly solution with risk of lower quality (added assembly steps increases a risk of defects) as compared to forming the piece integrally. *Second*, an integral divider wall will strengthen the tray allowing it to be stiffer and to maintain its intended shape.

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

(b) Limitation 17[b]

452. Limitation 17[b] requires “*a first syringe and a second syringe disposed within the first compartment, the first syringe containing lubricating jelly and the second syringe containing water, wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure.*”

⁵ Designing the mold to include an internal divider wall may require a more complex mold but designing such a mold is a one-time cost. In contrast, manufacturing parts using two different molds and adding a separate piece to the tray is a repeated cost. Thus, any additional upfront costs of an integral divider wall would likely be dwarfed by ongoing costs of a separate piece solution.

453. For the reasons in limitation 1[b], Numata discloses “*a first syringe and a second syringe disposed within the first compartment.*”

454. For the reasons in limitation 1[d], Numata in view of Serany discloses “*the first syringe containing lubricating jelly and the second syringe containing water.*”

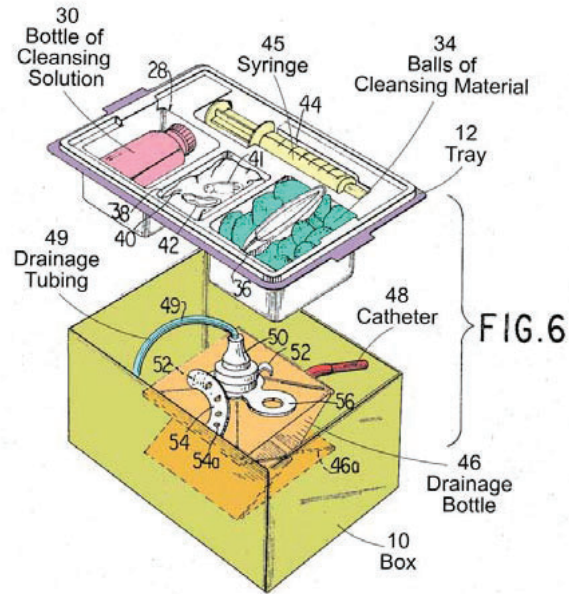
455. For the reasons in limitations 14[f] and [g], Solazzo in view of Serany and Imai discloses “*wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure.*”

(c) Limitation 17[c]

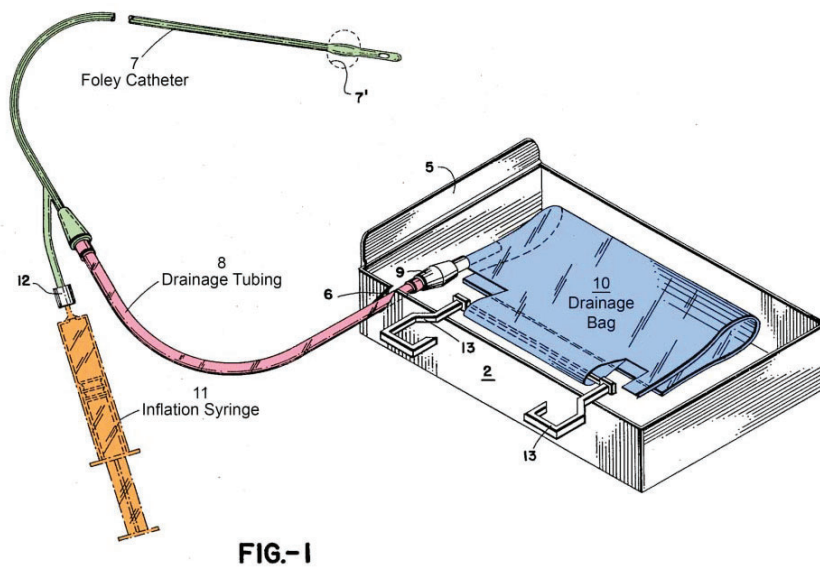
456. Limitation 17[c] requires “*the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment with the coiled tubing positioned between the Foley catheter and the fluid drain bag.*”

457. For the reasons at limitation 1[c], Numata in view of Serany and Disston disclose “*the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment.*”

458. Serany discloses “with the coiled tubing positioned between the Foley catheter and the fluid drain bag.” Specifically, Serany discloses that “drainage tubing 49” “connect[s]” the “catheter 48” to the “bottle 46” as shown in Figure 6. (Ex. 1009 at 3:32-35.)



459. Disston also discloses drainage tube 8 positioned between catheter 7 and drainage bag 10 as shown in Figure 1 below:



(Ex. 1008 at 2:19-23.)

460. To the extent Medline were to argue that “positioned between” requires the tubing to be arranged such that is positioned above the drainage bag and below the Foley catheter when situated in the second compartment, Solazzo in view of Serany and Disston still disclose this claim element.

461. As discussed at limitation 1[c], both Serany and Disston disclose storing the catheter, tubing, and catheter together with the tubing connecting the catheter and bag. As shown in Figure 6 of Serany, the collapsible drainage bag is at the bottom of box 10 (and “folded flat” when stored) so the drainage tubing 49 is thus necessarily positioned above it when stored. (Ex. 1009 at Fig. 6, 3:29-34.) The positioning of the Foley catheter is not entirely clear given only a portion of it is visible in Figure 6. However, it is connected to the drainage bag via the drainage tubing 49 so it too must be above the drainage bag, which is “folded flat” at the bottom of box 10. (Ex. 1009 at Fig. 6, 3:29-34.) Additionally, Serany states: “the catheter 48 is lubricated with the lubricating jelly 40 while the drainage bottle 46 and tubing 49 are still in the box 10.” (Ex. 1009 at 3:45-48.) A POSA would thus understand that Serany’s catheter would have been placed on top of the tubing, which is further on top of the drainage bag, since the catheter is removed from the box 10 before the drainage tubing. Such an arraignment is consistent with Serany’s teaching of “everything [being] available in the proper order of use.” (Ex. 1009 at 1:23-25.)

462. When adding the closed-system Foley catheter of Serany/Disston to Numata, it would have been obvious to a POSA to arrange the items of a closed-system Foley catheter in a top-to-bottom arrangement such that the drainage receptacle is on the bottom of the tray and the Foley catheter is provided on top with the coiled tubing positioned between them.

463. Serany provides motivation to arrange the items in this order by teaching arranging “components in their preferred order of use” and “proper order of use.” (Ex. 1009, 1:9-12; 1:23-25.) The Foley catheter is necessarily used before the tubing and drainage receptacle. Specifically, a clinician needs access to the Foley catheter to lubricate and insert it before the tubing and drainage bag are accessed. Upon accessing and inserting the Foley catheter, some amount of the coiled tubing will also be accessed and removed from the tray as shown by Disston (Ex. 1008, Fig. 1.) Finally, the drainage bag is accessed last and attached to the bed as discussed by Serany and Disston. (Ex. 1009 at 3:45-57; Ex. 1008 at 2:53-55.) Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Numata “*with the coiled tubing positioned between the Foley catheter and the fluid drain bag*” (if this claim language requires such an arrangement).

464. I understand that the Federal Circuit already accepted Bard’s argument that it would have been obvious to place a drainage bag under the Foley catheter given their order of use:

Here, the limitation amounts to no more than rearranging simple items (a fluid receptacle and catheter) in a tray. Serany's disclosure, coupled with common sense, would have provided a skilled artisan with ample motivation to place the fluid receptacle under the catheter; such an arrangement would conveniently place the items in the order they are used during the procedure.

C. R. Bard, 2021 WL 3574043, at *7.

465. By the same logic, it would have been obvious to position the coiled tubing between the Foley catheter and drainage bag as the tubing merely connects the Foley catheter and bag.

466. Accordingly, Numata in view of Serany and Disston discloses this claim element. Numata in view of Serany, Disston, and Imai therefore renders claim 17 obvious.

2. Claim 18

467. Claim 18 requires “*one or more swabsticks disposed within the single layer tray; a Foley catheter securement device disposed within the single layer tray; and a specimen jar disposed within the single layer tray.*”

468. For the reasons at claim 10, Numata in view of Salvadori discloses “*one or more swabsticks disposed within the single layer tray.*”

469. For the reasons at claim 10, Numata in view of Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*”

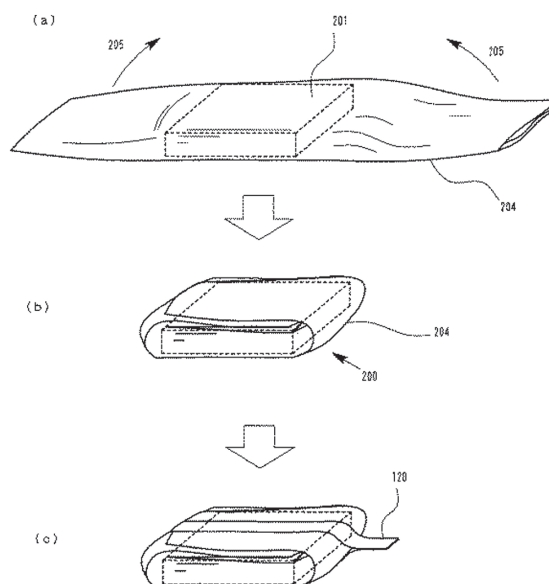
470. For the reasons at claim 6, Numata in view of Salvadori discloses “a specimen jar disposed within the single layer tray.”

3. Claim 19

471. Numata discloses “one or more layers of wrap material enclosing the single layer tray within one or more folds of the one or more layers of wrap material and an outer packaging disposed about the one or more folds of the one or more layers of wrap material.”

472. Numata discloses a single layer tray “wrapped with cover cloth 204” as shown in FIG. 5 (a) and (b). (Ex. 1007 ¶ 0031.) “As shown in FIG. 5 (a), the cover cloth 204 is laid over the medical instruments, etc., arranged in the tray 201 in FIG. 4, in the up-down direction in the drawing, and the left and right sides are folded over in the directions indicated by the arrows 205.” (Ex. 007 ¶ 0032.)

(FIG. 5)



(Ex. 1007 ¶¶ 0022-25; 0031-32.)

Numata also discloses “*an outer packaging disposed about the one or more folds of the one or more layers of wrap material*”—meaning about the “cover cloth 204.” As shown in Figure 7 below, packaging bag 100 is disposed about cover cloth 204. (Ex. 1007 at Abstract, Fig. 7. ¶¶ 0019-0020; 0022-25; 0031-32.)

4. Claim 20

473. For the reasons at claim 3, Numata in view of Beddow discloses or renders obvious “*the first compartment defining a lubricating jelly application compartment.*”

XI. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

474. 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 VI.C, the claims of the '347 Patent are nearly identical to the cancelled claims of related Medline patents. None of the additional claim limitation added by the '347 Patent such as “adjacent” compartments add anything with respect to secondary considerations of non-obviousness.

475. 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.)

476. 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.)

477. 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.)

478. 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.

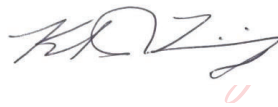
XII. CONCLUSION

479. 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.

480. 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

 Digitally signed by Karl R.
Leinsing
Date: 2025.01.03 11:29:02
-05'00'

Karl R. Leinsing, MSME, PE

Exhibit A



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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

To: 2002

IVAC/imed/Eli Lilly/ALARIS/Cardinal Health/CareFusion/BD

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)

<u>Patent No.</u>	<u>Issue Date</u>	<u>Title</u>
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

Curriculum Vitae of Karl R. Leinsing, MSME, PE

Printed: 10/22/24



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Published Patent Applications (others pending)

<u>Pub. No.</u>	<u>Pub. Date</u>	<u>Title</u>
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

Curriculum Vitae of Karl R. Leinsing, MSME, PE



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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

<u>Year</u>	<u>College/University</u>	<u>Degree</u>
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	<u>Novartis</u> 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. <u>R.J. Reynolds Vapor Company and Modoral Brands, Inc.</u>
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. <u>R.J. Reynolds Vapor Company and Modoral Brands, Inc.</u>
07/28/2021	2021-00816	9,220,631	<u>Novartis</u> vs. Regeneron / Pre-Filled Syringe
04/23/2022	2022-00917 2022-00918	10,980,452	Dexcom vs. <u>Abbott</u> / Glucose Sensor
04/22/2022	2022-00919 2022-00920	10,888,481	Mizuho vs. <u>Allen Medical & Hill-Rom</u> / Surgical Table
11/16/2022	2022-01347	11,002,646	Genotek vs. <u>Spectrum</u> / Sample Collection
11/18/2022	2022-00487 2022-00488	9,078,713 10,993,751	<u>Stryker</u> vs OsteoMed / Bone Plates
9/14/2023	2023-01424	11,536,632	Genotek vs. <u>Spectrum</u> / Sample Collection
07/20/2024	2023-01409	11,202,591	<u>Abbott</u> vs Dexcom / Continuous Glucose Monitor
9/24/2024	2023-01424	11,536,632	Genotek vs. <u>Spectrum</u> / 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