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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY

Petitioner

v.

Patent Owner of

U.S. Patent No. 5,704,914 to Stocking et al.

IPR Trial No. TBD

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 22-26, 28, 29, 31 OF U.S. PATENT NO. 5,704,914 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

FEDERAL STATUTES

REGULATIONS

REGULATIONS

I. MANDATORY NOTICES

A. Real Party In Interest

Becton, Dickinson and Company ("Petitioner") is the real party in interest and submits this Petition for *Inter Partes* Review ("Petition") for review of claims 22-26, 28, 29, and 31 of U.S. Patent No. 5,704,914 (the "'914 patent").

B. Related Matters

The following litigation matter would affect or could be affected by a decision in this proceeding: *One StockDuq Holdings, LLC v. Becton, Dickinson and Company,* 2:12-cv-03037 (W.D. Tenn.). The '914 patent has been asserted against Petitioner, and the asserted claims are the subject of this Petition.

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II. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies pursuant to Rule 42.104(a) that the patent for which review is sought is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting an *Inter Partes* Review challenging the patent claims on the grounds identified in this Petition.

III. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 22-26, 28, 29, and 31 of the '914 patent, (Ex. 1001) and requests that each challenged claim be cancelled.

A. Prior Art

Petitioner relies upon the following patents:

1. U.S. Patent 5,098,395 ("Fields;" Ex. 1002) to Fields, which issued on March 24, 1992 and is prior art under 35 U.S.C. § 102(b).
2. U.S. Patent 3,399,674 ("Pannier;" Ex. 1003) to Pannier et al., which issued on September 3, 1968 and is prior art under 35 U.S.C. § 102(b).
3. U.S. Patent 3,766,916 ("Moorehead;" Ex. 1005) to Moorehead et al., which issued on October 23, 1973 and is prior art under 35 U.S.C. § 102(b).
4. U.S. Patent 5,697,914 ("Brimhall;" Ex. 1006) to Brimhall, which was filed on March 16, 1995 and issued on December 16, 1997 and is prior art under 35 U.S.C. § 102(e).

5. U.S. Patent 4,468,224 ("Enzmann;" Ex. 1007), to Enzmann et al., which issued on August 28, 1984 and is prior art under 35 U.S.C. § 102(b).

6. U.S. Patent No. 4,205,675 ("Vaillancourt;" Ex. 1010), to Vaillancourt, which issued on June 3, 1980 and is prior art under 35 U.S.C. § 102(b).

7. U.S. Patent No. 4,068,659 ("Moorehead II;" Ex. 1011), to Moorehead, which issued on January 17, 1978 and is prior art under 35 U.S.C. § 102(b).

8. U.S. Patent No. 5,342,316 ("Wallace;" Ex. 1014), to Wallace, which issued on August 30, 1994 and is prior art under 35 U.S.C. § 102(b).

None of these patents were applied by the Examiner during prosecution of the '914 patent. Further, the only patents that were of record during the '914 patent prosecution were Vaillancourt and Moorehead II, which are presented here in a new light.

B. Grounds of Challenge

Petitioner requests cancellation of claims 22-26, 28, 29, and 31, the challenged claims, as unpatentable under 35 U.S.C. §§ 102 and 103. Attached to this petition is a declaration of Thomas M. Vesely, M.D. ("Vesely Decl."; Ex. 1004). Dr. Vesely's declaration supports the grounds in this petition showing that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each challenged claims is not patentable. *See* 35 U.S.C. § 314(a).

IV. LEGAL PRINCIPLES

The challenged claims are anticipated and/or obvious under 35 U.S.C. §§ 102 and 103, respectively. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g.*, *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Even if the certain claims are not anticipated under 35 U.S.C. § 102, the claims are invalid if they would have been obvious. In *KSR,* the Supreme Court addressed the issue of obviousness and provided an "expansive and flexible" approach consistent with the "broad inquiry" set forth in *Graham v. John Deere*. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415 (2007).

As the Supreme Court recognized, a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton" and "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420-21. Accordingly, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* at 421.

The Supreme Court in *KSR* specifically addressed whether the combination of known elements could be patentable if it yielded predictable results. The Court's holding was clear: it may not. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. Further, "[i]f a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability." *Id.* at 401. With respect to obviousness, the issue is whether an "improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

Based on the prior art described in this petition, it is clear that the challenged claims are either anticipated or at least are merely a predictable combination of old elements that are used according to their established functions.

V. CLAIM CONSTRUCTION

A claim subject to *Inter Partes* Review is given its "broadest reasonable construction in light of the specification in which it appears." 37 C.F.R. § 42.100(b). The broadest reasonable construction is the broadest reasonable interpretation of the claim language. *See In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 2004). Any claim term which lacks a definition in the specification is therefore also given a broad interpretation. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).

Solely for purposes of this proceeding, the following discussion proposes constructions of certain claim terms and identifies support for these constructions. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art.

Moreover, should the Patent Owner contend that the claims have a construction different from their broadest reasonable construction in order to avoid the prior art, the appropriate course is for the Patent Owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012).

A. The term "flexible, resilient diaphragm…for preventing the flow of a liquid"

Independent claims 31 and 22 recite the term, "flexible, resilient diaphragm…for preventing the flow of a liquid." The proposed construction is *a flexible, resilient seal that prevents the flow of a liquid*. *See* '914 patent, col. 4:24-30; Ex. 1001. One skilled in the art would interpret diaphragm, consistent with the specification, as being synonymous with a septum. The specification describes preferable liquid sealing means in the form of "a flexible, resilient diaphragm or septum 34" and does not distinguish between the terms. *Id.* Thus, any construction of the term diaphragm must also include a septum to be consistent with the specification.

B. The term, "diaphragm attached between said body and a proximal end of said hub"

Independent claim 22 recites the term "diaphragm attached between said body and a proximal end of said hub." The proposed construction is *a seal that is held in place in a space that separates the needle attachment body and a proximal end of the catheter hub*. *See* '914 patent, col. 4:35-45; Ex. 1001, The American Heritage Dictionary 179-80 (3d ed. 1996); Ex. 1013.

C. The term "at least one fenestration…with said hub lumen"

Independent claim 31 recites that the introducer needle includes, "at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and with said hub lumen." Independent claim 22 recites that the introducer needle includes, "at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and…with said hub lumen." The proposed construction of the limitation is that the introducer needle includes *one or more openings located closer to the center than to the ends of the needle that provides fluid flow from the needle cannula, through the opening(s) and into the hub when the openings are aligned with the hub*. *See* '914 patent, col. 3:67-4:6, col. 8:37-41, col. 5:34-40, Figs. 3, 9; Ex. 1001.

One skilled in the art would interpret central portion, consistent with the specification, as being closer to the center than to the ends of the needle. *See* '914 patent, col. 3:67-4:6, Figs. 1-6. Additionally, the functional relationship recited in

the claim between the needle fenestration(s) and the hub is described in the specification as being "properly positioned" when blood can flow from the needle cannula through the fenestrations and into the hub.[1] '914 patent, col. 5:34-40; Ex. 1001. For clarity, the Petitioner proposes "aligned" instead of "properly positioned."

VI. OVERVIEW OF THE '914 PATENT

A. Brief Description

The '914 patent (Ex. 1001) was filed as a patent application on February 23, 1996. The '914 patent describes an over-the-needle catheter assembly for insertion into a blood vessel or similar region of the body. '914 patent, col. 1:4-8; Ex. 1001; Vesely Decl. ¶ 20; Ex. 1004. Figure 3, reproduced below, demonstrates the various claimed features of the catheter assembly, as annotated by Dr. Vesely. Vesely Decl. ¶ 21; Ex. 1004.

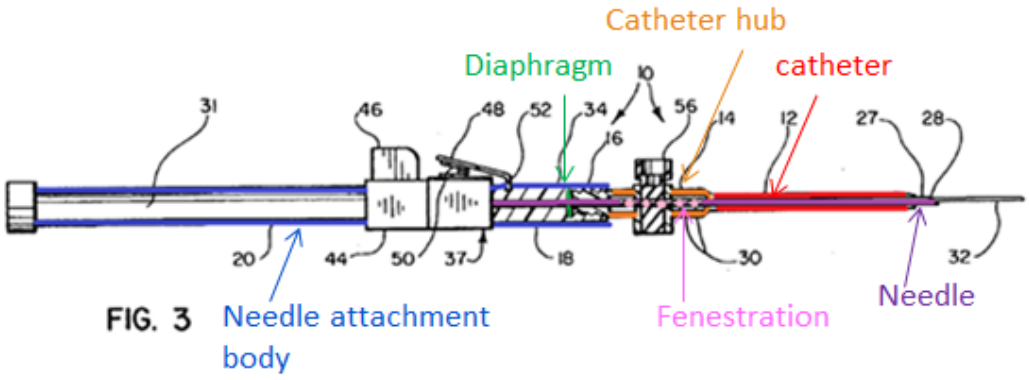


FIG. 3

[1] The Patent Owner describes the invention in a manner consistent with this proposed construction. *See* Amendment dated Feb. 21, 1997 at 13, 15; Ex. 1008.

The device claimed in the '914 patent is composed of various, standard features in catheter assemblies. The '914 patent acknowledges that devices for the introduction of catheters into blood vessels "have long been known and used." '914 patent, col. 1:14-16; Ex. 1001. Additionally, the '914 patent recognizes that catheter systems including a catheter hub and an introducer needle were also known. *Id.* at col. 1:26-28; Ex. 1001. Thus, catheter assemblies with a flexible catheter, a catheter hub, and a needle that passes through the catheter and is attached to a needle attachment body were well known by 1996.[2] Vesely Decl. ¶ 22; Ex. 1004. Indeed, not only were the components known, the combination of components recited in many of the challenged claims are anticipated by the prior art identified in this Petition.

The '914 patent identifies objectives for the disclosed catheter assembly. Specifically, it must: (1) prevent blood spillage and, (2) provide a visual indication of blood that allows the clinician to recognize that the device is properly inserted into a blood vessel (known as "flash back"). '914 patent, col. 1:8-11, Ex. 1001; Vesely Decl. ¶ 24; Ex. 1004. These "objectives" were known in the art. Vesely Decl. ¶ 23-24; Ex. 1004. The disclosed catheter assembly attempts to achieve these objectives through the use of a diaphragm and a fenestrated needle, both of

[2] References in this Petition to "1996" are prior to February 23, 1996.

which were known as of the filing date of the '914 patent. Vesely Decl. ¶ 24; Ex. 1004.

First, to prevent blood spillage the catheter assembly disclosed in the '914 patent requires a flexible, resilient diaphragm, which seals a proximal end of the catheter hub in a liquid tight manner. '914 patent, col. 12:14-22, col. 11:44-49; Ex. 1001. The '914 patent specification describes the "diaphragm or septum 34" as a type of liquid sealing means that "encloses the proximal end of the hub 14 in a liquid tight manner when in an unpenetrated condition insofar as the needle 27 is concerned as shown in FIGS. 4-5." *Id.* at col. 4:26-29; Ex. 1001; Vesely Decl. ¶ 25; Ex. 1004. The specification further states that the catheter assembly "contains a liquid sealing means in a catheter hub for substantially preventing a biological liquid introduced into the catheter from escaping the hub through the sealing means." '914 patent, col. 8:13-16; Ex. 1001; Vesely Decl. ¶ 25; Ex. 1004. By 1996, diaphragms, septums, plugs, and other sealing devices were well known in catheter assemblies to prevent blood leakage from a catheter hub. Vesely Decl. ¶ 25; Ex. 1004.

Second, to provide flashback the catheter assembly includes an introducer needle having a sharp tip and at least one fenestration on a central portion thereof, which communicates with the cannula of the needle and with the catheter hub lumen. '914 patent, col. 12:25-38; Ex. 1001. The '914 patent specification states

that the purpose of the fenestration is to allow visual recognition of blood flow to ensure proper venipuncture. *Id.* at col. 8:37-41, col. 1:8-11; Ex. 1001. The '914 patent specification further describes the location of the fenestrations, stating, "An elongate, cannulated catheter introducer needle 27, having a sharp beveled tip 28 at its distal end and at least one, but, preferably, a plurality of spaced apart fenestrations 30 formed along a central portion of its length. …" *Id.* at col. 3:67-4:6; Ex. 1001.

The specification further describes the structure of the fenestrations within the catheter assembly, noting,

> At this point, it should be noted that the diameter of the hub lumen must be somewhat greater than the outside diameter of the needle 27 so that blood or other body fluid introduced into the needle 27 can flow through one or more of the fenestrations 30 into the hub lumen 24 around the needle 27 when the needle 27 and the fenestrations 30 are properly positioned.

Id. at col. 5:34-40; Ex. 1001. As with diaphragms, the use of openings in needles for flashback was well known to one of ordinary skill in the art by 1996. Vesely Decl. ¶ 29; Ex. 1004. Additionally, it was also known to position holes in a central location on a needle. *Id.* ¶ 29. The claimed combination of features for preventing blood spillage and creating flashback are based on known elements functioning in known ways to yield predictable results. Vesely Decl. ¶ 29; Ex. 1004.

Beyond the basic features described above, in some claims the catheter assembly also includes a side access port 54 that communicates with the catheter hub lumen. '914 patent, col. 11:29; Ex. 1001. The side access port is shown in Fig. 5.

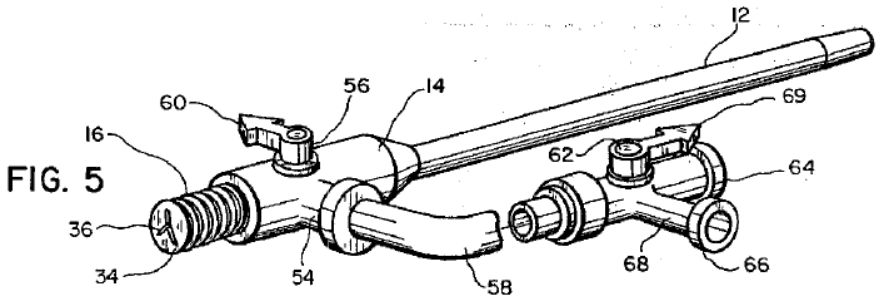


FIG. 5

Side access ports were also well known features in catheters by 1996. Vesely Decl. ¶ 30; Ex. 1004. Thus, by 1996, the claimed combination of features was merely known elements functioning in known ways to yield predictable results. Vesely Decl. ¶ 30; Ex. 1004.

B. Summary of the Prosecution History of the '914 Patent

During prosecution the Applicant amended the claims and argued their patentability in response to multiple rejections by the Examiner. The limitations added by the Applicant were all old and performed their expected function in expected ways. With respect to the challenged claims, the Applicant amended independent claim 22 (pending claim 23) and independent claim 31 (pending claim 25). Amendment dated Feb. 21, 1997 at 5-7; Ex. 1008. Applicant also added new

dependent claims 23-30 (pending claims 34-41). *Id.* at 9, 18; Ex. 1008. The added limitations to claim 22 (pending claim 23) include a needle attachment body, a needle defining at least one fenestration, and a diaphragm attached between said [needle attachment] body and a proximal end of said [catheter] hub. *Id.* at 5, 6, 15; Ex. 1008.

Consistent with the disclosed embodiment where the fenestrations are disposed in the hub in the operative position, the Applicant distinguished the prior art as failing to teach the alignment between the fenestrations and catheter hub. Specifically, in Paragraph III of the Remarks in the Amendment, the applicant distinguished the prior art by arguing:

> If, on the other hand, the adapter containing a diaphragm as taught by Clarke where [sic] applied to the assembly of Lewis, et al., as suggested, then … (B) none of the needle fenestrations would be disposed within the catheter hub as required by each of applicants' subject claims.

Id. at 13; Ex. 1008.

Later in the Remarks, when arguing the patentability claim 22 (pending claim 23), the Applicant said that the "same reasoning applies in response to this rejection as set forth in Paragraph III hereof relating to the rejection of claim 7." *Id.* at 15; Ex. 1008. The applicant did not identify anything unpredictable about the combination

of nor apply the standard of obviousness established by the Supreme Court's decision in *KSR*, which was decided after the '914 patent issued.

Following these amendments, the Examiner noted that the claims were allowable. Final Office Action dated May 12, 1997; Ex. 1009. None of the primary prior art references discussed in this petition were before the Examiner during the original prosecution of the patent.[3] However, each primary prior art reference presented below shows a needle with fenestrations disposed in the catheter hub—the very claim limitation that the Applicant argued for patentability of the claims.

The applicant also amended claim 31 (pending claim 25) to include a flexible, resilient diaphragm instead of a liquid sealing means. Amendment dated Feb. 21, 1997 at 6-7; Ex. 1008. To overcome the anticipation rejection, the Applicant only argued that the claim should be allowable "since it has also been amended herewith to include a 'flexible resilient diaphragm,' which is not shown or taught in Lewis, et al." *Id.* at 12; Ex. 1008. The Examiner subsequently noted that the claims were allowable without commenting on the obviousness of the combination. Final Office Action dated May 12, 1997; Ex. 1009. However, as

[3] Vaillancourt and Moorehead II were of record during the prosecution of the '914 patent application, but are being used as secondary references in this petition to show that flexible catheters were known in 1996.

demonstrated by the prior art references presented below, diaphragms were known elements in catheter assemblies by 1996.

Although the references relied upon by the Examiner during prosecution did not disclose a catheter assembly with a diaphragm, a needle attachment body, and a needle defining at least one fenestration, these elements were old and are disclosed in the references presented below.

VII. THE CHALLENGED CLAIMS ARE NOT PATENTABLE

The challenged claims recite features long known by clinicians who use IV catheters. The structures in the claimed catheter assembly all have known functions that perform in expected ways. Based on the prior art described below, the claim limitations perform known functions with predictable results and there is no unexpected result on which to base the patentability of the claims.

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Vesely Declaration (Ex. 1004) show in detail the prior art disclosures that makes the challenged claims anticipated and obvious.

A. Independent claim 31 is Not Patentable

1. Claim 31 is Anticipated by Moorehead

Moorehead discloses a catheter placement unit 2 that includes an over the needle catheter assembly. *See* Moorehead, col. 2:9-12, Fig. 3; Ex. 1005. As shown in the claim chart below, the catheter placement unit 2 includes a catheter 4

attached at its proximal end 10 to a catheter hub, referenced as sleeve 14 and central unit 6. *See* Moorehead, Figs. 1, 3; Ex. 1005. Moorehead inherently discloses that the catheter is flexible because it can be made from several materials, including polytetrafluorethylene (PTFE), which is commonly known as a flexible material in the medical community. *Id.* at col. 2:13-17; Ex. 1005, Vesely Decl. ¶ 36; Ex. 1004.

Further, Moorehead discloses that the sleeve 14 and central unit 6 are a catheter hub as the claim term would be understood under the broadest reasonable interpretation standard. The male fitting 30 of central unit 6 mates with the bore 20 of sleeve 14 and is "preferably secured therein by a suitable bonding agent, such as epoxy." Moorehead, col. 2:31-35; Ex. 1005. Thus, one of ordinary skill in the art would understand sleeve 14 and central unit 6, which are bonded together, to be a hub. Vesely Decl. ¶ 39; Ex. 1004.

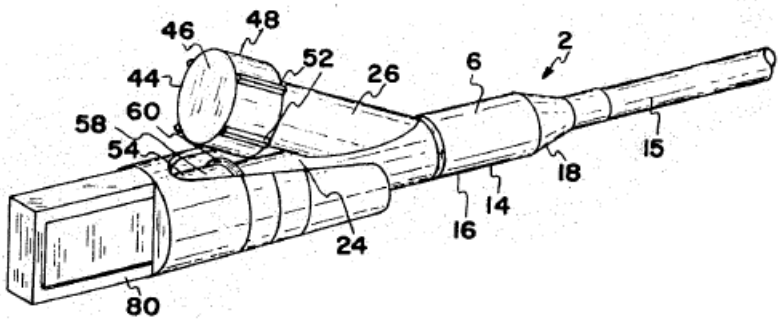


FIG. 1

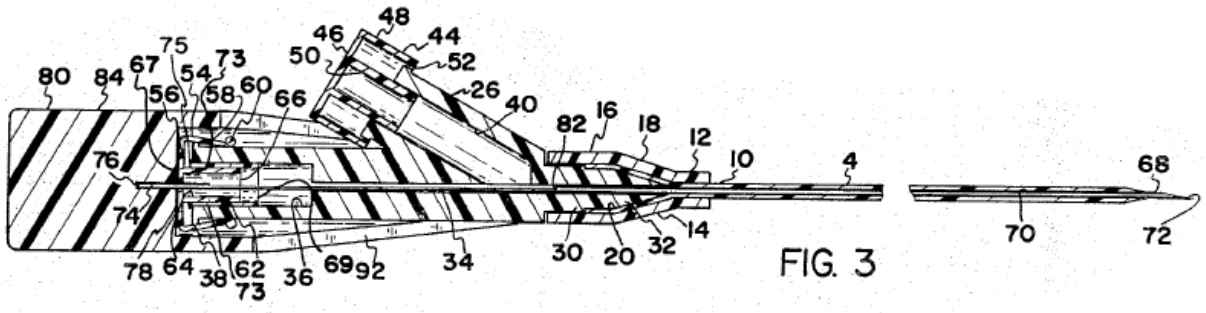


FIG. 3

The catheter placement unit 2 further includes a flexible, resilient diaphragm, referenced as plug 54 with self-sealing wall 67, which seals around the needle and closes to form a seal after the needle is withdrawn. *See* Moorehead, col. 2:58-60, col. 2:67-col. 3:6, Figs. 3-5; Ex. 1005. One of ordinary skill in the art understands that the self-sealing wall 67 of the plug 54 functions as a diaphragm. Vesely Decl. ¶ 40; Ex. 1004. Further, the elastomeric material of the plug, such as latex, is understood to be flexible and resilient, as required by the claim. Moorehead, col. 2:58-60; Ex. 1005, Vesely Decl. ¶ 40; Ex. 1004.

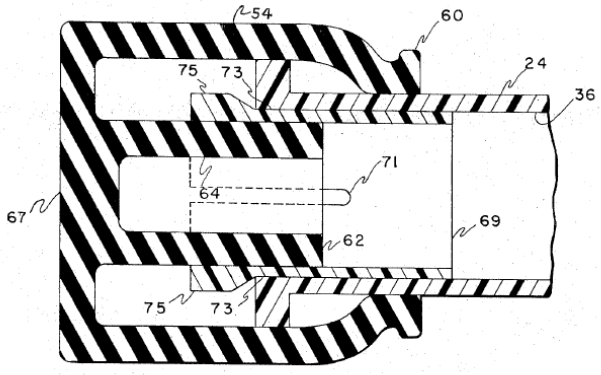


FIG. 4

The catheter placement unit 2 includes a needle attachment body, referenced as tab member 80 and shell portion 90 that is removably connected to the hub, and a cannulated catheter introducer needle 68 having a sharpened bevel point 72 and defining a fenestration, referenced as elongated opening 82, on a central portion of the needle 68 that communicates with the cannula of the needle 68 and with the lumen of the hub (sleeve 14 and central unit 6). *See* Moorehead, Fig. 3; Ex. 1005.

Thus, as illustrated below, Moorehead anticipates claim 31 because it discloses all of the claim limitations.

Claim	Moorehead (Ex. 1005)
31. A catheter assembly comprising	*See, e.g.,* Moorehead, col. 2:9-12.
a flexible catheter defining a passageway which extends between open proximal and distal ends,	*See, e.g.,* Moorehead, col. 2:9-17, Fig 3.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which extends between open proximal and distal ends and which communicates on a distal end thereof with said passageway,	*See, e.g.,* Moorehead, col. 2:16-38, Figs. 1, 3.
a flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub,	*See, e.g.,* Moorehead, col. 1:43-47, col. 2:58-60, col. 2:67-col. 3:6, col. 3:57-63, col. 4:51-53, Figs. 2-5.

a needle attachment body removably connected to said hub, and	*See, e.g.,* Moorehead, col. 3: 28-39, 53-59, Figs. 1-3.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to project through said diaphragm, hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and with said hub lumen and which is positioned distally of said diaphragm when said introducer needle is disposed in said operative position.	*See, e.g.,* Moorehead, col. 3:16-28, col. 3:43-49, Fig. 3.

2. Claim 31 is Obvious over Moorehead in view of Vaillancourt

As presented above, all of the limitations recited in claim 31 are disclosed explicitly or inherently by Moorehead, and the above analysis is incorporated by reference herein. The Patent Owner may identify that Moorehead does not use the term "flexible" to describe the catheter. However, a catheter made from the PTFE material identified by Moorehead is flexible. Vesely Decl. ¶¶ 36-37; Ex. 1004. The presence of this limitation in the prior art should not be disputed. If the Patent Owner disputes whether a catheter made from PTFE would have been flexible, U.S. Patent No. 4,205,675 ("Vaillancourt") provides that catheters are preferably made of flexible materials and identifies polytetrafluorethylene (PTFE) as one such

material. Vaillancourt, col. 6:46-51, col. 2:10-11, col. 1:32; Ex. 1010, Vesely Decl. ¶ 36; Ex. 1004.

The limitation reciting the "hub" is also clearly disclosed Moorehead. The Patent Owner may attempt to distinguish Moorehead by arguing, incorrectly, that claim 31 requires a "one-piece" catheter hub**.** The Patent Owner would have no basis in the claim or the specification for interpreting the term catheter hub as a "one piece" catheter hub.

Even under this narrow reading of the hub limitation, it would have been obvious to design the two-piece central unit 6 and sleeve 14 disclosed in Moorehead as a one-piece catheter hub. Vesely Decl. ¶ 46; Ex. 1004. As previously discussed, Moorehead discloses that the sleeve 14 and central unit 6 are preferably connected with a bonding agent and thus function as a one-piece body to a clinician using the device. Moorehead, col. 2:31-35; Ex. 1005, Vesely Decl. ¶ 46; Ex. 1004. Thus, the design of a one-piece catheter hub is merely a combination of familiar elements yielding predictable results, and is obvious. *See KSR,* 550 U.S. at 401.

Finally, the Patent Owner cannot credibly argue that the introducer needle in Moorehead does not include at least one fenestration as recited in the claim. As previously discussed, the term fenestration includes openings and does not specify a size. Vesely Decl. ¶ 47; Ex. 1004. Thus, the opening 82 is a fenestration to one

of ordinary skill in the art. *Id.* ¶ 47; Ex. 1004. At least part of the opening is located on a central portion of the needle. Moorehead, col. 3:25-28, Fig. 3; Ex. 1005, Vesely Decl. ¶ 47; Ex. 1004. The opening 82 performs the same function as the claimed fenestrations because, when the needle is in its operative position, the opening communicates with a cannula of said introducer needle and with said hub lumen.

The use of one, elongated opening 82 on a needle as described in Moorehead or "one or more" fenestrations as disclosed and claimed in the '914 patent would be a matter of routine design choice because they function in the same way. *See* Vesely Decl. ¶¶ 48-50; Ex. 1004. It would have been obvious to design the needle with fenestrations as opposed to an elongated opening because the combination is merely familiar elements performing their known function to yield predictable results. *See KSR,* 550 U.S. at 401. Thus, claim 31 is obvious.

3. Claim 31 is Obvious over Fields in view of Vaillancourt or Moorehead II

Fields discloses a catheter over the needle connector assembly that prevents blood exposure. *See* Fields, col. 1:67-col. 2:2; Ex. 1002. As shown in the claim chart below, the catheter assembly, referenced as connector 10, includes a catheter 34 attached to a catheter hub comprising hub 38 and second member 28, and a needle attachment body comprising first connector member 12 with hub 36, which is removably connected to the second member 28. *See* Fields, Fig. 1; Ex. 1002.

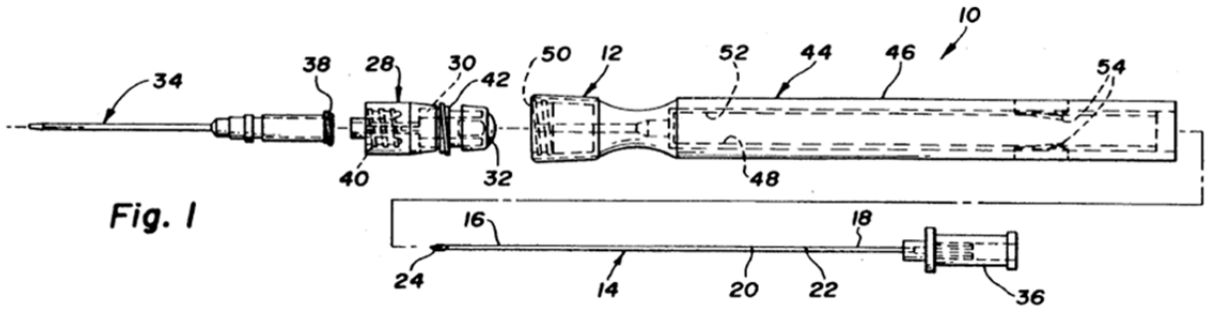


Fig. 1

The assembly also includes a needle 14 with an opening 20 that is located in the flashback chamber 30 of the second member 28. The assembly has a diaphragm comprising a rubber septum 32. *See* Fields, Fig. 3; Ex. 1002.[4]

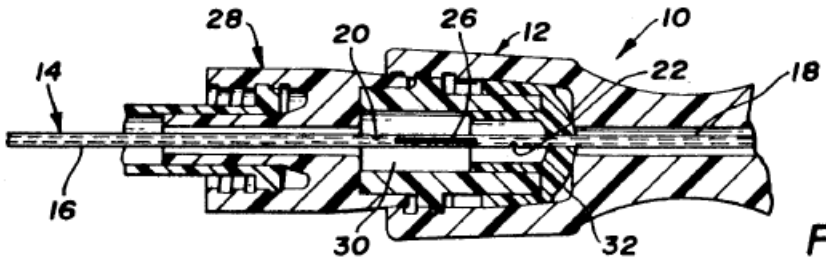


Fig. 3

As illustrated below, all of the limitations are obvious based on the combination of Fields in view of Vaillancourt or Moorehead II.

Claim	Fields (Ex. 1002)
31. A catheter assembly comprising	*See, e.g.,* Fields, col. 3:28-31; Fig. 1.
a flexible catheter defining a passageway which extends between open proximal and distal ends,	*See, e.g.,* Fields, col. 4:9, Fig. 1. *See, e.g.,* Vaillancourt, col. 6:46-51, col. 2:10-11, col.

[4] Rubber material is flexible and resilient, as required by the claim. Vesely Decl. ¶ 52; Ex. 1004.

	1:32; Ex. 1010 *See, e.g.,* Moorehead II, col. 2:37-41, col. 1:53-57, col. 2:11-25; Ex. 1011.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which extends between open proximal and distal ends and which communicates on a distal end thereof with said passageway,	*See, e.g.,* Fields, col. 4:9-17, col. 3:50-57, col. 4:50-54, Fig. 1.
a flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub,	*See, e.g.,* Fields, col. 3:50-57, col. 3:65-col.4:3, Figs. 1-3. *See, e.g.,* Fields II, col. 3:68-4:7; Ex. 1012.
a needle attachment body removably connected to said hub, and	*See, e.g.,* Fields, col. 2:54-65, col. 3:36-39, col. 3:49-50, col. 4:4-6, col. 4:18-24, col. 3:50-51, Fig. 1.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to project through said diaphragm, hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which	*See, e.g.,* Fields, col. 3:36-43, col. 3:53-4:6, Figs. 1, 3.[5]

[5] One of ordinary skill in the art understands that the term, fenestration, is a broad term that includes openings. Vesely Decl. ¶ 52; Ex. 1004.

communicates with a cannula of said introducer needle and with said hub lumen and which is positioned distally of said diaphragm when said introducer needle is disposed in said operative position.	

The only feature of claim 31 not expressly disclosed in Fields is a "flexible" catheter. By 1996, flexible catheters were well known and routinely used.[6] Vesely Decl. ¶ 55; Ex. 1004. By this time flexible catheters were the standard of care. *Id.* ¶ 97; Ex. 1004. Vaillancourt and Moorehead II disclose flexible catheters to reduce vein trauma and patient discomfort. Vaillancourt, col. 6:46-51, col. 2:10-11, col. 1:32; Ex. 1010, Moorehead II, col. 2:37-41, 1:53-57, 2:11-25; Ex. 1011.

Fields discloses that the catheter is placed in the patient's vein and provides a fluid path. Fields, col. 3:53-57, col. 4:9-11; Ex. 1002. As the Supreme Court has stated, "The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results." *See KSR,* 550 U.S. at 416. Thus, "[i]f a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability. *Id.* at 401. It would have been obvious to one of ordinary skill in the art to use a flexible catheter to reduce vein trauma and patient

[6] The term, "flexible" is not defined by a quantitative value in the '914 patent and is thus a relative term. Vesely Decl. ¶ 55; Ex. 1004.

discomfort when the catheter is providing a fluid path in a patient. Vesely Decl. ¶ 56; Ex. 1004.

Further, the Patent Owner may attempt to distinguish Fields by arguing, incorrectly, that claim 31 requires a one-piece catheter hub. As previously discussed, the Patent Owner would have no basis in the claim or in the specification for interpreting the term catheter hub as a "one piece" catheter hub.

Even under this narrow reading of the hub limitation, it would have been obvious to design the two-piece hub 38 and second member 28 disclosed in Fields as a one-piece catheter hub. Vesely Decl. ¶¶ 57-58; Ex. 1004. Fields discloses that the second connector member includes "a flashback chamber having a rubber septum and also including a catheter tip mounted thereon." Fields, col. 4:50-54, col. 3:50-53; Ex. 1002. Thus, Fields discloses that the catheter 34 and hub 38 may be mounted on second member 28 and function as a one-piece body to a clinician using the device. Vesely Decl. ¶ 57; Ex. 1004. Further, the Fields device could still connect to other devices as intended through a connector attached at the connecting means 42. Fields, col. 4:9-17; Ex. 1002, Fields II, col. 3:64-col. 4:7, Figs. 1-4; Ex. 1012, Vesely Decl. ¶ 58; Ex. 1004. Thus, the design of a one-piece catheter hub is merely a combination of familiar elements yielding predictable results, and thus is obvious. *See KSR,* 550 U.S. at 401.

Finally, the Patent Owner cannot credibly argue that rubber septum in Fields does not prevent the flow of liquid through the proximal end of the hub. Fields describes a connector that minimizes contact with a patient's blood. *See generally* Fields, col. 1:11-15; Ex. 1002. The rubber septum 32 is positioned at the proximal end of the flashback chamber, and one of ordinary skill in the art would understand that the septum was intended to act in a predictable manner to prevent fluid flow beyond the chamber. *Id.* at col. 3:50-col. 4:3, Figs. 1, 3; Ex. 1002; Vesely Decl. ¶ 59; Ex. 1004.

Additionally, Fields incorporates by reference the disclosure in the applicant's earlier U.S. Application 592,134, which issued as U.S. Patent 5,088,984 ("Fields II"), and discloses medical connectors for use when administering fluids to a patient. *See* Fields, col. 3:24-28, col. 4:14-17; Ex. 1002; Fields II, col. 1:5-9; Ex. 1012. Thus, the disclosure of various connectors in Fields II is effectively part of Fields. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282-83 (Fed. Cir. 2000).

Fields II, like Fields, discloses a rubber septum but expressly describes the septum as preventing spillage. *See* Fields, col. 3:50-57; Ex. 1002; Fields II, col. 3:68- col. 4:7, Figs. 2, 3 (not labeled); Ex. 1012. Thus, it would have been obvious to design a diaphragm that prevents the flow of liquid through the proximal end of the hub in view of the rubber septum discloses in Fields (including the description

incorporated by reference from Fields II) to minimize contact with blood by preventing blood spillage from the device.

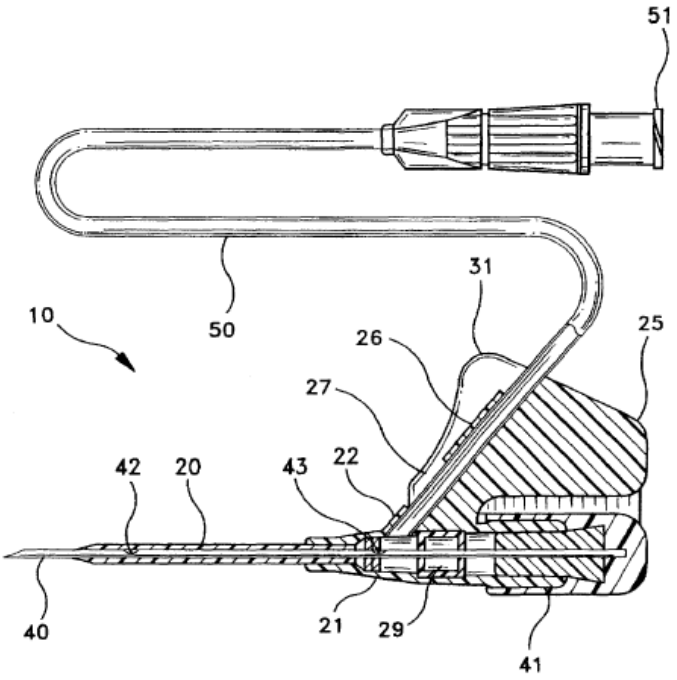
4. Claim 31 is Anticipated by Brimhall

Brimhall discloses a catheter and introducer needle assembly 10. *See* Brimhall, col. 3:6-9, Fig. 2; Ex. 1006. As shown in the claim chart below, the catheter and introducer needle assembly 10 includes a flexible catheter 20 attached to a catheter hub 21. Brimhall discloses a flexible catheter to one of ordinary skill in the art by stating, "Needle 40 provides column strength to catheter 20 as it is advanced into the vein." Brimhall, col. 4:34-35; Ex. 1006, Vesely Decl. ¶ 61; Ex. 1004. One of ordinary skill in the art in 1996 would understand that the catheter needs column strength from the needle because the catheter is flexible, and thus it is not rigid enough to retain its shape as it is advanced into the vein. Vesely Decl. ¶ 61; Ex. 1004.

The catheter assembly also includes a diaphragm, referenced as elastomeric plug 29, attached to the hub 21 to seal a proximal end of the hub, and a needle attachment body, referenced as needle hub 41, connected to the hub 21. *See* Brimhall, Fig. 2; Ex. 1006. The catheter and introducer needle assembly also includes a catheter introducer needle 40 with a sharp tip that projects through the elastomeric plug 29, the lumen of hub 21, and the catheter 20 when it is in an operative position for insertion, the needle 40 including a fenestration, referenced

as notch 43, located on a central portion of the needle that communicates with the lumen of hub 21 and the needle 40. *See id.* at col. 3:49-58, Fig. 2; Ex. 1006.

FIG–2



Thus, as illustrated below, all of the limitations of claim 31 are disclosed by Brimhall.

Claim	**Brimhall patent (Ex. 1006)**
31. A catheter assembly comprising	*See, e.g.,* Brimhall, col. 3:6-9, Figs. 2, 4.
a flexible catheter defining a passageway which extends between open proximal and distal ends,	*See, e.g.,* Brimhall, col. 3:9-10, col. 3:17-22, col. 4:34-35, Fig. 1.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which extends between open proximal and distal ends and which communicates on a distal	*See, e.g.,* Brimhall, col. 3:8-12, col. 3:17-22, Figs. 1, 2.

end thereof with said passageway,	
a flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub,	*See, e.g.,* Brimhall, col. 3:22-25, col. 3:52-55, Figs. 2, 4.
a needle attachment body removably connected to said hub, and	*See, e.g.,* Brimhall, col. 3:46-47, col. 3:59-62, col. 4:35-37.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to project through said diaphragm, hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and with said hub lumen and which is positioned distally of said diaphragm when said introducer needle is disposed in said operative position.	*See, e.g.,* Brimhall, col. 3:49-col. 4:1, col. 4:20-28, col. 4:39-42, Fig. 2.

5. Claim 31 is Obvious over Brimhall in view of Vaillancourt or Moorehead II

As illustrated above, all of the limitations recited in claim 31 are disclosed by Brimhall, and the above analysis is incorporated by reference herein. The

Patent Owner may identify that that Brimhall does not use the term "flexible" to describe the catheter. A catheter that requires column strength from a needle as it is advanced into the vein is a flexible catheter. *See* Brimhall, col. 4:34-35; Ex. 1006, Vesely Decl. ¶ 64; Ex. 1004.

The presence of this limitation in the prior art should not be a disputed item. However, if the Patent Owner disputes whether the catheter is flexible, Vaillancourt and Moorehead II provide that catheters are made of flexible materials to reduce vein trauma and patient discomfort. Vaillancourt, col. 6:46-51, col. 2:10-11, col. 1:32; Ex. 1010, Moorehead II, col. 2:37-41, 1:53-57, 2:11-25; Ex. 1011. Thus, it would have been obvious to one of ordinary skill in the art to use a flexible catheter to reduce vein trauma and patient discomfort due to the catheter during infusion therapy. Vesely Decl. ¶¶ 65-66; Ex. 1004.

The Patent Owner may also identify that Brimhall does not use the term "diaphragm" to describe its seal. Brimhall discloses an elastomeric plug that seals the proximal end of the catheter hub. Brimhall, col. 3:22-25; Ex. 1006. The plug is understood to be flexible and resilient because it is elastomeric, and the plug is disclosed to be penetrated by the needle, as required by the claim. Vesely Decl. ¶ 68; Ex. 1004; Brimhall, Fig. 2; Ex. 1006. The '914 patent does not provide any specific information regarding the structure or purpose of the diaphragm that is not met by the elastomeric plug disclosed in Brimhall. Diaphragms and plugs were

well known in the prior art as seals that prevent fluid flow. Vesely Decl. ¶ 68; Ex. 1004. As the Supreme Court recognized in *KSR*, the simple substitution of one known element for another to obtain predictable results is obvious. 550 U.S. at 417. Because both elements (the diaphragm and the plug) were well known in the art, it would have been obvious to one of ordinary skill in the art to merely substitute a diaphragm for an elastomeric plug.

B. Independent claim 22 is Not Patentable

1. Claim 22 is Anticipated by Moorehead

Claim 22 largely recites the limitations in claim 31,[7] but adds the additional limitation of "a side access port communicating with said hub lumen." Side ports were well known structures in catheter assemblies, and this additional limitation does not make claim 22 patentable, as described in more detail below.

As previously described with respect to claim 31, *supra* Section VII(A)(1) and incorporated by reference herein, Moorehead discloses a catheter placement unit 2. *See* Moorehead, col. 2:9-12, Fig. 3; Ex. 1005. Moorehead also discloses a side access port, referenced as cylindrical arm 26 with axial bore 40, that

[7] Claim 22 recites similar limitations to claim 31, but generally with less specificity. The analysis of claim 31 in view of the references applies to the analysis for claim 22.

communicates with the bore 34 of the arm 24 of central unit 6. *See* Moorehead, col. 2:28-31, col. 2:44-45, Figs. 1, 3; Ex. 1005.

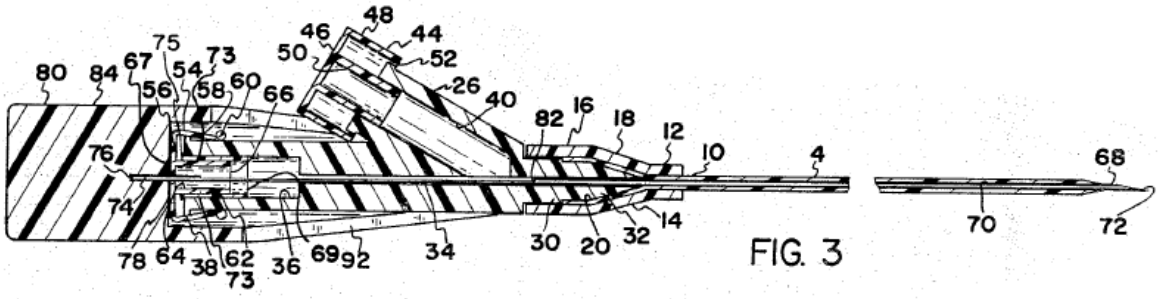


FIG. 3

Thus, as illustrated below, all of the limitations of claim 22 are disclosed by Moorehead.

Claim	Moorehead (Ex. 1005)
22. A catheter assembly comprising	*See, e.g.,* Moorehead, col. 1:5-6, col. 2:9-12.
a flexible catheter defining a passageway extending between open proximal and distal ends,	*See, e.g.,* Moorehead, col. 2: 9-17, Fig. 3.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which communicates with said passageway	*See, e.g.,* Moorehead, col. 2:16-38, Figs. 1, 3.
a side access port communicating with said hub lumen,	*See, e.g.,* Moorehead, col. 2:28-31, col. 2:44-45, col. 2:47-51, Fig. 3.
a needle attachment body connected to said hub, and	*See, e.g.,* Moorehead, col. 3:19-25, col. 3:28-39, Figs. 1-3.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to project	*See, e.g.,* Moorehead, col. 3:16-23, col. 3:43-49, col. 3: 25-28; Fig. 3.

through said hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and, when said introducer needle is in said operative position, with said hub lumen and,	
a flexible resilient diaphragm attached between said body and a proximal end of said hub proximal to said side access port for preventing the flow of a liquid through said hub lumen past said side access port and through the proximal end of said hub external to said introducer needle cannula.	*See, e.g.,* Moorehead, col. 1:43-47, col. 2:58-60, col. 2:67-col. 3:6, col. 4:51-53, Figs. 2-5.

2. Claim 22 is Obvious over Moorehead in view of Vaillancourt

The limitations recited in claim 22 are obvious over Moorehead in view of Vaillancourt. The analysis of claim 22 presents similar issues to those addressed with respect to claim 31, *supra* Section VII(A)(2), relating to the flexibility of the catheter, the two-piece nature of the hub, and the elongated opening. The arguments for claim 31 apply with equal force to claim 22, and are incorporated by reference herein. Thus, claim 22 is obvious over Moorehead in view of Vaillancourt.

3. Claim 22 is Obvious over Fields in view of Vaillancourt or Moorehead II

Claim 22 largely recites the limitations in claim 31,[8] but adds the additional limitation of "a side access port communicating with said hub lumen." Side ports were well known structures in catheter assemblies, and this additional limitation does not make claim 22 patentable, as described in more detail below.

As previously described with respect to claim 31, *supra* Section VII(A)(3) and incorporated by reference herein, Fields discloses a catheter over the needle connector assembly that prevents blood exposure. *See* Fields, col. 1:67-col. 2:2, Fig. 1; Ex. 1002. As previously discussed, Fields incorporates by reference Fields II, and the disclosure of various connectors in Fields II is effectively part of Fields. *See* Fields, col. 3:24-28, col. 4:14-17; Ex. 1002; Fields II, col. 1:5-9; Ex. 1012, *Advanced Display Sys.,* 212 F.3d at 1282-83.

Fields recognizes that numerous connectors may be used in catheter assemblies, Fields, col. 3:24-31; Ex. 1002, and one of the connector embodiments disclosed in Fields II includes a side port and a diaphragm, described as a branch connector with a rubber septum. *See* Fields II, col. 4:31-42, Fig. 3; Ex. 1012.

[8] Claim 22 recites similar limitations to claim 31, but generally with less specificity. The analysis of claim 31 in view of the references applies to the analysis for claim 22.

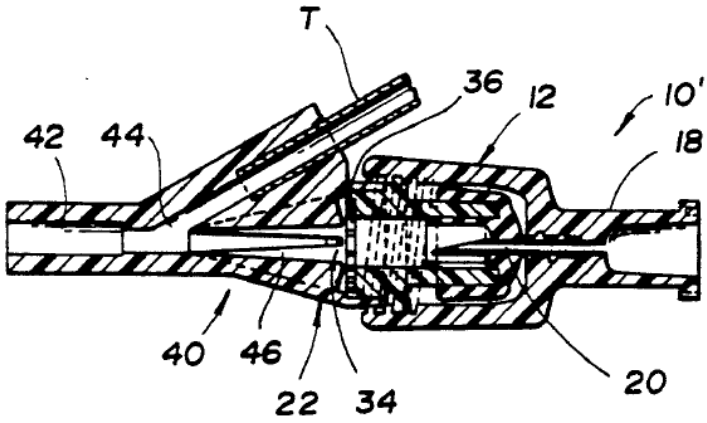


Fig. 3

As illustrated below, all of the limitations are obvious over Fields, which also incorporates by reference the disclosure in Fields II, in view of Vaillancourt or Moorehead II.

Claim	Fields (Ex. 1002)
22. A catheter assembly comprising	*See, e.g.,* Fields, col. 3:28-31, Fig. 1.
a flexible catheter defining a passageway extending between open proximal and distal ends,	*See, e.g.,* Fields, col. 4:9, Fig. 1. *See, e.g.,* Vaillancourt, col. 6:46-51, col. 2:10-11, col. 1:32; Ex. 1010 *See, e.g.,* Moorehead II, col. 2:37-41, col. 1:53-57, col. 2:11-25; Ex. 1011.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which communicates with said passageway	*See, e.g.,* Fields, col. 4:9-17, col. 3:50-57, col. 4:50-54, Fig. 1.
a side access port communicating with said hub lumen,	*See, e.g.,* Fields, col. 3: 24-25. *See, e.g.,* Fields II, col. 4:31-42; Fig. 3; Ex. 1012.
a needle attachment body connected to said hub,	*See, e.g.,* Fields, col. 3:36-39,

and	3:49-50, 4:4-6, 4:18-24, 3:50-51, Fig. 1.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to project through said hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and, when said introducer needle is in said operative position, with said hub lumen and,	*See, e.g.,* Fields, col. 3:36-43, col. 3:53-4:6, Fig. 1, 3.
a flexible resilient diaphragm attached between said body and a proximal end of said hub proximal to said side access port for preventing the flow of a liquid through said hub lumen past said side access port and through the proximal end of said hub external to said introducer needle cannula.	*See, e.g.,* Fields, col. 3:50-57, col. 3:65-col. 4:3, Figs. 1-3. *See, e.g.,* Fields II, col. 3:68-4:7; Ex. 1012.

The limitations recited in claim 22 are obvious over Fields, which incorporates by reference the disclosure in Fields II, in view of Vaillancourt or Moorehead II. The analysis of claim 22 presents similar issues to those address with respect to claim 31, *supra* Section VII(A)(3), relating to the flexibility of the catheter, the two-piece nature of the hub, and the rubber septum. The arguments

for claim 31 apply with equal force to claim 22, and are incorporated by reference herein.

It would have been obvious to one of ordinary skill in the art to provide a side access port in communication with the hub lumen at least because the disclosure in Fields II has these features. Fields II discloses a branch connector 40 that is a "conventional 'Y' connector." Fields II, col. 4:31-40; Ex. 1012. One of ordinary skill in the art would understand that a "Y" connector can be used for various purposes, including the establishment of two fluid flow paths. *See* Vesely Decl. ¶ 78; Ex. 1004.

Although the "Y" connector disclosed in Fields II is shown upstream of the catheter assembly in Fig. 7, it is also used at the site of the catheter assembly. *See* Fields II, Fig. 3; Ex. 1012. The connector 10' in Fields II has a flashback chamber and thus would typically be placed near the site of entry to ensure timely flashback of blood upon proper venipuncture. Fields II, col. 4:39-42; Ex. 1012, Vesely Decl. ¶ 79; Ex. 1004. Thus, one of ordinary skill in the art would understand that flashback would be a useful feature if it were located near the catheter assembly.

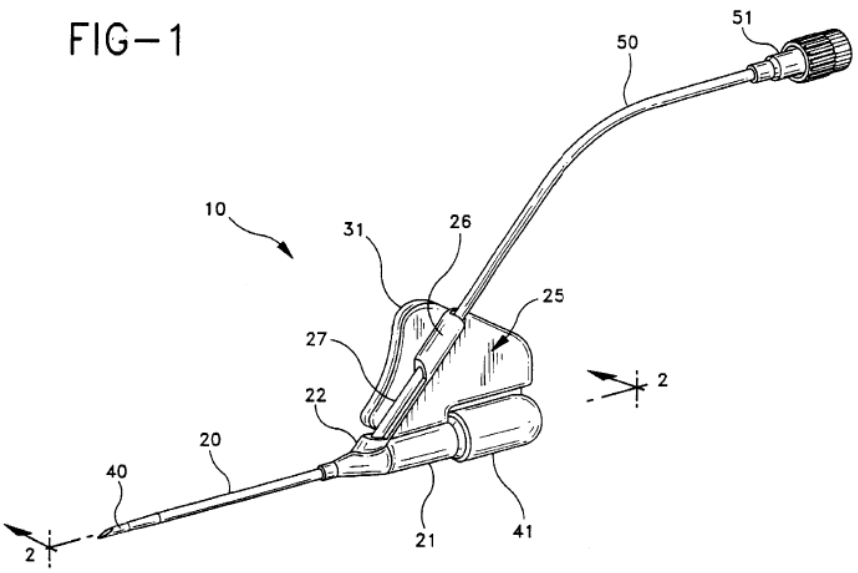
The Patent Owner cannot credibly argue that the branch connector 40 in connector 10' of Fields II could not be physically combined at the connection means 42 of the device shown in Fields. *See* Fields, col. 4:14-17, Fig. 1; Ex. 1002. The obviousness inquiry does not ask "whether the references could be physically

combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole." *In re Etter,* 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc); *see also In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981). Thus, it would have been obvious to design a catheter assembly as disclosed in Fields with a side access port that is in communication with the catheter hub lumen because it would simplify the device and the combination is nothing more than a combination of prior art elements that yields a predictable solution. *See KSR,* 550 U.S. at 401, 421.

4. Claim 22 is obvious over Brimhall in view of Fields

Claim 22 largely recites the limitations in claim 31, but adds the additional limitation of "a side access port communicating with said hub lumen." Side ports were well known structures in catheter assemblies, and this additional limitation does not make claim 22 patentable, as described in more detail below.

As previously described with respect to claim 31, *supra* Section VII(A)(4) and incorporated by reference herein, Brimhall discloses a flexible catheter and introducer needle assembly 10. *See* Brimhall, col. 3:6-9; Ex. 1006. Brimhall also discloses a side port 22 that communicates with the catheter 20, and thus necessarily communicates with the hub 21. *See id.* at col. 2:10-11, col. 3:17-22, Figs. 1, 2; Ex. 1006.



Thus, as illustrated below, all of the limitations of claim 22 are obvious over Brimhall in view of Fields.

Claim	Brimhall patent (Ex. 1006)
22. A catheter assembly comprising	*See, e.g.,* Brimhall, col. 3:6-9, Figs. 2, 4.
a flexible catheter defining a passageway extending between open proximal and distal ends,	*See, e.g.,* Brimhall, col. 3:9-10, col. 3:17-22, col. 4:34-35, Fig. 1.
a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which communicates with said passageway	*See, e.g.,* Brimhall, col. 3:8-12, col. 3:17-22, Figs. 1, 2.
a side access port communicating with said hub lumen,	*See, e.g.,* Brimhall, col. 3;10-11, col. 3:17-22, col. 4:60-64, Figs. 1, 2.
a needle attachment body connected to said hub, and	*See, e.g.,* Brimhall, col. 3:46-47, col. 3:59-62.
a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has at least one position relative to said body which is operative to	*See, e.g.,* Brimhall, col. 3:49-col. 4:1, col. 4:20-28, col. 4:39-42, Fig. 2.

project through said hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and, when said introducer needle is in said operative position, with said hub lumen and,	
a flexible resilient diaphragm attached between said body and a proximal end of said hub proximal to said side access port for preventing the flow of a liquid through said hub lumen past said side access port and through the proximal end of said hub external to said introducer needle cannula.	*See, e.g.,* Brimhall, col. 3:22-25, col. 3:52-55, Figs. 2, 4. *See, e.g.,* Fields, col. 3:50-57, col. 3:65-col. 4:3, Figs. 1-3.

The analysis of claim 22 largely presents similar issues to those addressed with respect to claim 31, *supra* Section VII(A)(4). The arguments for claim 31 apply with equal force to claim 22. Additionally, claim 22 differs from claim 31 in that it requires "a flexible, resilient diaphragm attached between said [needle attachment] body and a proximal end of said [catheter] hub." In contrast, claim 31 requires the diaphragm to be "attached to said hub."[9]

[9] Claims 31 and 22 recite potentially different locations for the diaphragm. As previously discussed, during prosecution of the application that issued as the '914 patent, the Applicant amended claim 22 (original claim 23) to recite a "diaphragm attached between said body and a proximal end of said hub." Amendment dated

Brimhall discloses that "[t]he proximal end of catheter hub 21 is sealed with an elastomeric plug 29 … to ensure that fluid does not leak out of the proximal end of catheter hub 21." Brimhall, col. 3:22-25; Ex. 1006. The elastomeric plug 29 is attached completely within the catheter hub. *Id.* at Figs. 2, 4; Ex. 1006.

Fields discloses that second member 28 has a flashback chamber having a rubber septum 32. Fields, col. 3:50-57, Figs. 1-3; Ex. 1002. As shown in Figs. 1 & 3, the septum 32 is attached between the second connector member 28 and the first connector member 12.

While not needed for the combination, Wallace provides ample motivation for a person of ordinary skill in the art to combine Brimhall and Fields so that the septum is positioned between the catheter hub and the needle attachment body. Wallace discloses an injection site with a resealable diaphragm that can be penetrated with a needle or a syringe. Wallace, col. 1:6-8, col. 1:20-29, col. 5:45-49; Ex. 1014. Wallace explains that the injection site may be swabbed, which "is necessary to disinfect the external surface of the diaphragm to prevent

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Feb. 21, 1997 at 6; Ex. 1008. In contrast, claim 31 (original claim 25) recites a "diaphragm being attached to said hub." *Id.* at 6; Ex. 1008. The Applicant did not comment on the different language, and instead specifically argued the location of the fenestrations within the hub (which is not expressly recited in the claim) to distinguish the prior art. *Id.* at 6, 13, 15; Ex. 1008.

contamination of the conduit contents." *Id.* at col. 1:15-19; Ex. 1014. Wallace discloses that the arrangement of the diaphragm may be changed, in this case to make it easier to swab. *Id.* at col. 5:39-45; Ex. 1014.

It would have been obvious to change the arrangement of the elastomeric plug 29 in Brimhall so that it is attached in a space between the hub and the needle attachment body as shown in Fields. By 1996, Wallace illustrates that it was known to one of ordinary skill in the art that the location of the diaphragm could be moved within the catheter hub. These references are directed to medical devices with a seal that may be penetrated and still prevent fluid spillage. Vesely Decl. ¶ 89; Ex. 1004. Thus, it would have been obvious to one of ordinary skill in the art to move the elastomeric plug 29 so that it is attached between the needle hub 41 (i.e., the body), and the proximal end of catheter hub 21 when that arrangement was known, the prior art recognizes that diaphragm arrangements may be changed, and the diaphragm yields a predictable result by sealing the proximal end of the catheter hub in this arrangement. *Id.* ¶ 89; Ex. 1004, *KSR*, 550 U.S. at 401, 416.

5. Claim 22 is obvious over Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II

The analysis of claim 22 largely presents similar issues to those addressed with respect to claim 31, *supra* Section VII(A)(5), relating to the flexibility of the catheter and the elastomeric plug. The arguments for claim 31 apply with equal force to claim 22, and are incorporated by reference herein.

Further, as discussed above *supra* Section VII(B)(4) and incorporated by reference herein, it would have been obvious in view of Brimhall and Fields to move the elastomeric plug 29 so that it is attached between the needle hub 41 (i.e., the body), and the proximal end of catheter hub 21 when that arrangement was known in Fields, and Wallace recognized that diaphragm arrangements may be changed. Vesely Decl. ¶ 91; Ex. 1004. Thus, the catheter assembly recited in claim 22 is obvious over Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II.

C. Claims 31 and 22 are Obvious over Moorehead in view of Fields or Brimhall

As previously described, *supra* Sections VII(A)(1) and VII(B)(1) and incorporated by reference herein, Moorehead discloses a catheter placement unit 2. *See* Moorehead, col. 2:9-12, Fig. 3; Ex. 1005.

The Patent Owner cannot credibly argue that the introducer needle with an elongated opening 82 in Moorehead does not include at least one fenestration as recited in the claims. As previously discussed the term fenestration includes openings, and does not specify a size. Vesely Decl. ¶ 47; Ex. 1004.

However, even under this narrow reading of the fenestration limitation, it would have been obvious to one of ordinary skill in the art in view of Fields or Brimhall to have a needle with a smaller opening. Fields discloses first opening 20 located on the needle in the flashback chamber 30, which is in the hub (second

connector member 28). Fields, col. 3:58-61, Fig. 1; Ex. 1002. The opening allows for visual confirmation of a successful stick due to the presence of blood in the flashback chamber 30. *Id.* at 3:65-col. 4:3; Ex. 1002. Thus, Fields discloses an opening that meets the limitations of a fenestration as claimed.

Similarly, Brimhall discloses notch 43 located on the needle 40 in the catheter hub 21 distal of the elastomeric plug 29. Brimhall, col. 3:49-58, Fig. 2; Ex. 1006. In the Brimhall device blood flows from the cannula of needle 40, through the notch 43, into catheter hub 21, up side port 22, and into extension tube 50 to provide blood flashback. *Id.* at col. 4:20-28, Fig. 2; Ex. 1006. Thus, Brimhall also discloses a notch that meets the limitations of a fenestration as claimed.

It would have been obvious to one of ordinary skill in the art to combine the opening disclosed in Fields or Brimhall with the catheter placement unit of Moorehead at least because all of the patents disclose catheter assemblies aimed at providing a visual indication of venipuncture by providing for fluid flow through an opening in the needle, where the opening is in the hub distal of the seal. Moorehead even discloses that the needle may be replaced with a conventional needle with a blood flashback chamber. Moorehead, col. 3:39-42; Ex. 1005. The substitution of a smaller opening or hole at a central portion of the needle instead of an elongated opening would perform the same function in the Moorehead device

and allow the flow of blood into bore 40 of arm 26 to provide a visual indication of venipuncture. Thus, it would have been obvious to design the needle with smaller openings as opposed to an elongated opening because the substitution of one known element for another known element yields only a predictable result. *See KSR,* 550 U.S. at 416.

D. Claims 31 and 22 are Obvious over Fields or Brimhall, in view of Moorehead

As previously described, *supra* Sections VII(A)(3)-(4) and VII(B)(3)-(4) and incorporated by reference herein, Fields and Brimhall each discloses a catheter assembly. *See* Fields, Fig. 1 (connector 10); Ex. 1002, Brimhall, Fig. 2 (catheter and introducer needle assembly 10); Ex. 1006. The Patent Owner may improperly argue that Fields or Brimhall does not disclose a flexible catheter or a flexible resilient diaphragm. Even under this narrow reading, the limitations would have been obvious to one of ordinary skill in the art in view of Moorehead.

Moorehead discloses a catheter made from polytetrafluorethylene, which is commonly known as a flexible catheter material in the medical community. Moorehead, col. 2:13-17; Ex. 1005, Vesely Decl. ¶ 97; Ex. 1004. By 1996, flexible catheters were well known and routinely used. Vesely Decl. ¶ 97; Ex. 1004. By this time flexible catheters were the standard of care to reduce vein trauma and patient discomfort. *Id.* ¶ 97; Ex. 1004, *e.g.,* Vaillancourt, col. 6:46-51, col. 2:10-11, col. 1:32; Ex. 1010; Moorehead II, col. 2:37-41, 1: 53-57, 2:11-25;

Ex. 1011. Thus, by 1996 one of ordinary skill in the art would expect that a catheter assembly used to penetrate a vein would include a flexible catheter. Vesely Decl. ¶ 97; Ex. 1004.

Additionally, Moorehead discloses a flexible resilient diaphragm to one of ordinary skill in the art. Vesely Decl. ¶ 98; Ex. 1004. Plug 54 with self-sealing wall 67 seals around the needle and closes to form a seal after the needle is withdrawn, and it is made of a flexible and resilient material, such as latex. *See* Moorehead, col. 2:58-60, col. 2:67-col. 3:6, col. 3:57-63, Figs. 3-5, Vesely Decl. ¶ 98; Ex. 1004.

It would have been obvious to one of ordinary skill in the art to provide a catheter assembly with a flexible resilient diaphragm in the place of a rubber septum (Fields patent) or an elastomeric plug (Brimhall patent) because all of these structures provide liquid seals. Also, with respect to claim 22, it would have been obvious to attach the flexible, resilient diaphragm between the needle attachment body and the proximal end of the catheter hub, as disclosed in Moorehead.[10] Thus,

[10] While not needed for the combination, Wallace provides ample motivation for a person of ordinary skill in the art to combine Brimhall and Moorehead so that the septum is positioned between the catheter hub and the needle attachment body. Wallace discloses an injection site with a resealable diaphragm that may be swabbed to prevent contamination. Wallace, col. 1:15-19; Ex. 1014. Wallace

it would have been obvious to design a catheter assembly with a flexible catheter and a diaphragm because the combination is merely familiar elements performing their known function to yield predictable results. *See KSR,* 550 U.S. at 401.

E. Claims 31 and 22 are Obvious over Moorehead or Fields in view of Vaillancourt or Moorehead II, in view of Pannier

As previously described, *supra* Sections VII(A)(1) and VII(B)(1) and incorporated by reference herein, Moorehead discloses a catheter placement unit 2. *See* Moorehead, col. 2:9-12, Fig. 3; Ex. 1005. Additionally, as previously described, *supra* Sections VII(A)(3) and VII(B)(3) and incorporated by reference herein, Fields discloses a catheter assembly (i.e., connector 10). *See* Fields, Fig. 1; Ex. 1002

The Patent Owner may attempt to distinguish these references by arguing, incorrectly, that the claims require a one-piece catheter hub. The Patent Owner would have no basis in the claim or in the specification for interpreting the hub as a one-piece hub.

Even under this narrow reading of the hub limitation, it would have been obvious to design the two piece catheter hub of Moorehead or Fields into a one-piece hub in view of Pannier. The Pannier patent discloses a catheter assembly

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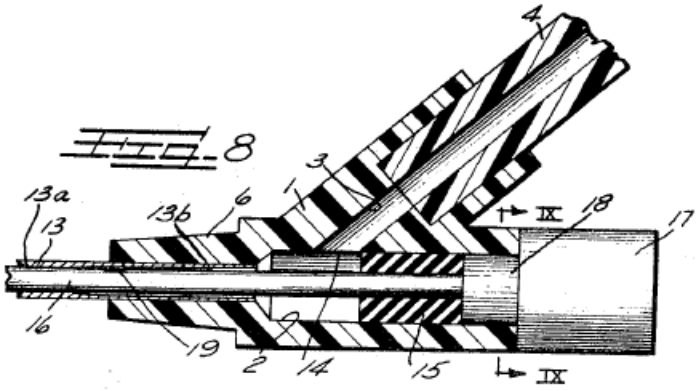
discloses that the arrangement of the diaphragm may be changed to make it easier to swab. *Id.* at col. 5:39-45; Ex. 1014.

including a catheter 13 attached to a one-piece catheter hub (i.e., fitting 1) with a hub lumen (i.e., passage 2) and a diaphragm (i.e., self-sealing plug 15). *See* Pannier, Figs. 7, 8, col. 3:54-74; Ex. 1003.

With respect to Moorehead, it would have been obvious to design the bonded sleeve 14 and central unit 6 in the Moorehead patent as a one-piece hub in view of Pannier. *See* Moorehead, col. 2:28-35, Fig. 1; Ex. 1005, Vesely Decl. ¶ 105; Ex. 1004. The sleeve 14 and central unit 6 of Moorehead perform the same function with the same fluid pathways as the one-piece catheter hub in Pannier. *See* Moorehead, Fig. 3; Ex. 1005, Pannier, col. 3:54-74, Figs. 7, 8; Ex. 1003. Thus, the design of a one-piece catheter hub is merely a combination of familiar elements yielding predictable results, and is obvious. *See KSR,* 550 U.S. at 401.

With respect to Fields, it would have been obvious to design the catheter hub in the Fields patent as a one-piece hub in view of Pannier. Fields discloses that the catheter 34 and hub 38 may be mounted on second member 28 and act as a one-piece body, such as fitting 1 in Pannier, to a clinician using the device. Fields, col. 4:50-54, col. 3:50-53; Ex. 1002, Vesely Decl. ¶¶ 57, 108; Ex. 1004. As previously discussed, a one piece hub design would still allow the Fields device to connect to other devices as intended. Thus, the design of a one-piece catheter hub is merely a combination of familiar elements yielding predictable results, and thus is obvious. *See KSR,* 550 U.S. at 401.

Regarding claim 22, designing a one-piece catheter hub with a side access port that communicates with the hub lumen would have been obvious in view of Pannier. Pannier discloses a side access port (i.e., passage 3 and tube 4) that communicates with the hub lumen, referenced as passage 2 in Pannier. *See* Pannier, col. 3:49-52, col. 2:46-51, Figs. 6-8; Ex. 1003.



It would have been obvious to design a side access port communicating with the hub lumen. As discussed *supra* Section VII(B)(3) (and incorporated by reference herein), Fields incorporates by reference disclosure of a branch connector that has a flashback chamber. Further, providing a side access port distal to the diaphragm would simplify the device by reducing the number of connectors, and would function in the same way by providing communication between the side access port and the hub lumen. Thus, the design of a one-piece catheter hub with a side access port is merely a combination of familiar elements yielding predictable results, and thus is obvious. *See KSR,* 550 U.S. at 401.

F. The Dependent Claims recite Additional Features that are Not Patentable

1. Dependent claim 23 recites the side access port formed on the hub, which is Anticipated and Obvious

Claim 23 depends from claim 22, which as discussed *supra* is not patentable in view of the previously discussed prior art. Claim 23 further limits claim 22 by reciting that the "side access port is formed on said hub." Side ports were well known structures in catheter assemblies, and they were known to be formed on the catheter hub. Thus, this additional limitation does not make claim 23 patentable.

The side port in Moorehead, referenced as cylindrical arm 26, is formed on the hub, referenced as central unit 6 and sleeve 14. *See* Moorehead, col. 2:28-31, col. 2:42-44, Fig. 3; Ex. 1005. Thus, claim 23 is anticipated by Moorehead and obvious over the same references applied to claim 22, namely Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, and Moorehead in view of Pannier.

Additionally, the side port 22 in Brimhall is formed on the hub 21. *See* Brimhall, col. 3:10-11, Fig. 1; Ex. 1006. Thus, claim 23 is obvious over the same references applied to claim 22, namely Brimhall in view of Fields, Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II, and Brimhall in view of Moorehead.

As discussed above with respect to claim 22, and incorporated by reference herein, it would have been obvious in view of Fields to design the catheter assembly with the branch connection at the hub, referenced as the second member 28, in view of the branch connector 40 (e.g., "Y" connector) with the second conduit 44 as disclosed in Fields II. Vesely Decl. ¶ 115; Ex. 1004. It would have been obvious to one of ordinary skill in the art to design a side access port on the hub because the "Y" connector can include flashback (Fields II, col. 4:39-42; Ex. 1012), which would be a useful feature if it were located in the hub like the flashback chamber 30 described in Fields. Fields, col. 3:50-52, Figs. 1, 3; Ex. 1002, Vesely Decl. ¶ 115; Ex. 1004. Thus, claim 23 is obvious over the same references applied to claim 22, namely Fields in view of Vaillancourt or Moorehead II, and Fields in view of Moorehead.

Additionally, as discussed above with respect to claim 22 *supra* Section VII(E), and incorporated by reference herein, it would have been obvious in view of Fields in view of Vaillancourt or Moorehead II, and further in view of Pannier to design the catheter assembly with a side access port formed on the hub. Pannier discloses a hub (i.e., fitting 1) with a side access port (i.e., branch passage 3 and tube 4) that communicates with the hub lumen, referenced as passage 2 in Pannier and is formed in fitting 1. *See* Pannier, col. 3:49-52, col. 2:46-51, Figs. 6-8; Ex. 1003, Vesely Decl. ¶ 117; Ex. 1004. Thus, claim 23 recites nothing more than a

combination of old elements according to known methods that yields predictable results, and therefore is not patentable in view of the references applied.

2. Dependent claim 24 recites a stop cock, which is Obvious

Claim 24 depends from claim 22, which as discussed *supra* (and incorporated by reference herein) is not patentable in view of the previously discussed prior art. Claim 24 further limits claim 22 and recites, "further comprising a multi-position stop cock operatively connected to said access port for selectively closing said access port in a liquid tight manner to prevent the flow of a liquid from said hub lumen through said access port." Stop cocks and multi-position stop cocks were well known structures used in catheter assemblies to direct the flow of fluid. Thus, this additional limitation does not make claim 24 patentable.

Enzmann discloses a stopcock that selectively prevents liquid flow, stating, "The stopcock valve 75 includes two inlet ports 76, 77 each having a Luer fitting 79, 80 thereon. A valve actuator 78 controls the admission of fluid through one of the inlet ports 76, 77 or closes off both ports under manual control." Enzmann, col. 9:50-54, Fig. 8; Ex. 1007. Thus, Enzmann discloses a multi-positioned stop cock that selectively prevents the flow of a liquid through inlet port 76, inlet port 77, or both inlet ports.

Using a multi-position stop cock operatively connected to said access port to control liquid flow in a catheter assembly would have been obvious to one of ordinary skill in the art. A stopcock was well known in the prior art as a device that controls fluid flow. Vesely Decl. ¶ 120; Ex. 1004. The claimed function of a stopcock to prevent fluid flow is also a well-known characteristic of stopcocks.

Further, Fields, Moorehead, and Brimhall in view of Fields disclose catheter systems with a side port configuration for fluid flow. As the Supreme Court has stated, "The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results." *See KSR*, 550 U.S. at 416. Thus, "[i]f a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability." *Id*. at 401. Therefore, it would have been obvious to one of ordinary skill to provide a stopcock operatively connected to the access port for selectively closing the access port to predictably control the flow of fluid. Thus, claim 24 is obvious over Enzmann in combination with the same references applied to claim 22, namely Moorehead, Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, Moorehead in view of Pannier, Fields in view of Vaillancourt or Moorehead II, Fields in view of Moorehead, Fields in view of Vaillancourt or Moorehead II, and further in view of Pannier, Brimhall in view

of Fields, Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II, and Brimhall in view of Moorehead.

3. Dependent claims 25 and 26 recite a transparent and a translucent hub, which are Anticipated and Obvious

Claims 25 and 26 depends from claim 22, which as discussed *supra* (and incorporated by reference herein) is not patentable in view of the previously discussed prior art. Claim 25 further limits claim 22 by reciting that the "hub is at least partially transparent." Claim 26 further limits claim 22 by reciting that the "hub is at least partially translucent." Transparent or translucent catheter hubs were well known in catheter assemblies. Thus, this additional limitation does not make claims 25 or 26 patentable.

Several of the references render obvious a hub that is at least partially transparent or at least partially translucent because the references disclose devices that allow the user to visually confirm that the device is properly inserted by viewing blood flow. Visual indication of blood flow would only be possible if the hub is at least partially transparent or translucent. The '914 patent even recognizes that the function is to allow observation of flash back blood, stating, "It is a further object of our invention to provide a catheter assembly which includes a transparent or translucent hub attached to the catheter for observing blood flash back in a lumen thereof.…" '914 patent, col. 2:22-25; Ex. 1001. The '914 patent does not distinguish between the benefits of a translucent or transparent hub, and one of

ordinary skill in the art would understand that either a transparent or translucent hub would provide for visual indication and is a mere design choice. *See* Vesely Decl. ¶ 123; Ex. 1004. Thus, a modification to make the hubs at least partially transparent or translucent would merely yield a predictable result that allows the prior art catheter devices to operates as described and provide visual indication of blood flow.

The hub in Moorehead, referenced as sleeve 14 and central unit 6, has a bifurcated transparent body 22. *See* Moorehead, col. 2:28-29; Ex. 1005. Thus, the hub is at least partially transparent, and claim 25 is anticipated by Moorehead and obvious over Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, and Moorehead in view of Pannier. Further, Moorehead explains that the arms of central unit 6 provide a visual indication that venipuncture has been achieved by showing blood flow and that the hub is transparent. *Id.* at col. 3:53-57, col. 2:28-29, col. 1:50-56; Ex. 1005. It would have been obvious to one of ordinary skill in the art to design a translucent catheter hub instead of a transparent hub because both allow visualization of blood flow and the selection is merely a design choice. *See* Vesely Decl. ¶ 125; Ex. 1004. Thus, claim 26 is obvious over the same references applied to claim 22, namely Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, and Moorehead in view of Pannier.

Additionally, Fields emphasizes the importance of visual confirmation of a successful venipuncture by the presence of blood in the flashback chamber 30 located in the second connector member 28, *see* Fields, col. 3:67-col. 4:1; Ex. 1002, and incorporates by reference disclosure that the flashback chamber "is made from a clear plastic material." Fields II, col. 2:28-30; Ex. 1012. Thus, it would have been obvious to design a clear, transparent hub in the Fields device to see blood flashback, and claim 25 is obvious. Further, it would have been obvious to one of ordinary skill in the art to design a hub that is at least partially translucent because it would also allow the clinician to see the blood in the flashback chamber in the hub. Vesely Decl. ¶¶ 126-127; Ex. 1004. Thus, claims 25 and 26 are obvious over the same references applied to claim 22, namely Fields in view of Vaillancourt or Moorehead II, Fields in view of Moorehead, and Fields in view of Vaillancourt or Moorehead II, and further in view of Pannier.

Brimhall discloses that flashback blood will only be visible if the components are transparent or translucent, specifically referencing the catheter and window 27 in the extension tube 50 of the hub. Brimhall, col. 4:20-28; Ex. 1006. Further, Brimhall discloses that the tubular member 26 may be made of a clear material so that flashback can be seen. *Id.* at col. 3:41-45; Ex. 1006. Thus, it would have been obvious to one of ordinary skill in the art to design a transparent or translucent catheter hub in addition to the window and catheter to view

flashback blood sooner and to ensure proper insertion of the device. Vesely Decl. ¶ 128; Ex. 1004. Claims 25 and 26 are obvious over the same references applied to claim 22, namely Brimhall in view of Fields, Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II, and Brimhall in view of Moorehead.

4. Dependent claim 28 recites that the body is removably connected to the hub, which is Anticipated and Obvious

Claim 28 depends from claim 22, which as discussed *supra* (and incorporated by reference herein) is not patentable in view of the previously discussed prior art. Claim 28 further limits claim 22 by reciting that the "needle attachment body is removably connected to said hub." As previously discussed with respect to claim 31, *supra* Section VII(A), removable needle attachment bodies were well known structures in catheter assemblies. Thus, this additional limitation does not make claim 28 patentable.

In each prior art reference discussed, the needle attachment body is removable. *See* Fields, col. 3:50-51, 4:18-24 (disclosing connector means 50 that allows the guard in first connector member 12 to be connected to the flashback chamber in the second member 28), Fig. 1; Ex. 1002; Moorehead, col. 3:28-39, 53-59, Figs. 2, 3 (disclosing tab member 80 and shell portion 90 attached to the central unit 6 via fingers 92 when the needle is in the catheter, and removed from the central unit 6 when the needle is withdrawn); Ex. 1005; Brimhall, col. 3:46-47,

59-62, col. 4:35-37 (disclosing needle hub 41 engaged with catheter hub 21 when the needle is inserted into the catheter, and removed when the needle is withdrawn from the catheter and hub); Ex. 1006, Vesely Decl. ¶ 130; Ex. 1004. Thus, claim 28 is anticipated by Moorehead and obvious over the same references applied to claim 22, namely Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, and Moorehead in view of Pannier. Further, this limitation is obvious over Fields in view of Vaillancourt or Moorehead II, Fields in view of Moorehead, Fields in view of Vaillancourt or Moorehead II, and further in view of Pannier, Brimhall in view of Fields, Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II, and Brimhall in view of Moorehead.

5. Dependent claim 29 recites that the diaphragm is directly attached to the hub, which is Anticipated and Obvious

Claim 29 depends from claim 22, which as discussed *supra* (and incorporated by reference herein) is not patentable in view of the previously discussed prior art. Claim 29 further limits claim 22 by reciting that the "diaphragm is directly attached to said catheter hub." Diaphragms were well known structures in catheter assemblies, and they were known to be directly attached to the hub. Thus, this additional limitation does not make claim 29 patentable.

In each prior art reference discussed, the diaphragm is directly attached to the hub. Vesely Decl. ¶ 132; Ex. 1004. The diaphragm in Moorehead, referenced

as plug 54 with self-sealing wall 67, is press-fit into a portion of the catheter hub, referenced as arm 24 of central unit 6. *See* Moorehead, col. 2:28-31, 58-60, Fig. 3; Ex. 1005. Thus, claim 29 is anticipated by Moorehead and obvious over the same references applied to claim 22, namely Moorehead in view of Vaillancourt, Moorehead in view of Fields or Brimhall, and Moorehead in view of Pannier.

Additionally, the diaphragm in Fields, referenced as rubber septum 32, is attached to a portion of the catheter hub, referenced as second member 28. *See* Fields, col. 3:50-57, Fig. 1; Ex. 1002. Thus, claim 29 is obvious over the same references applied to claim 22, namely Fields in view of Vaillancourt or Moorehead II, Fields in view of Moorehead, and Fields in view of Vaillancourt or Moorehead II, and further in view of Pannier.

The diaphragm in Brimhall, referenced as plug 29, is located in and seals the proximal end of the catheter hub 21. *See* Brimhall patent, col. 3:22-25, Figs. 2, 4; Ex. 1006. Thus, claim 29 is obvious over the same references applied to claim 22, namely Brimhall in view of Fields, Brimhall in view of Fields, and further in view of Vaillancourt or Moorehead II, and Brimhall in view of Moorehead because it recites nothing more than a combination of old elements yielding predictable results, and is therefore not patentable in view of the references applied.

Based on the foregoing, claims 22-26, 28, 29, and 31 of the '914 patent recite subject matter that is either anticipated or obvious. The primary references

cited above were never considered by the original Examiner, and if they had been, the '914 patent would not have issued. The Petitioner requests institution of an *Inter Partes* Review to cancel those claims.

Respectfully submitted,

Becton, Dickinson and Company,

Petitioner

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CERTIFICATE OF SERVICE

I hereby certify that, on April 4, 2013, I caused a true and correct copy of the foregoing materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 5,704,914
- Exhibits 1001-1014
- Exhibit Appendix
- Fee Authorization Page
- BD Power of Attorney

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EXHIBIT APPENDIX

Exhibit	Description
BD 1001	The '914 patent (U.S. Patent No. 5,704,914)
BD 1002	The Fields patent (U.S. Patent No. 5,098,395)
BD 1003	The Pannier patent (U.S. Patent No.3,399,674)
BD 1004	The Declaration of Thomas Vesely, M.D.
BD 1005	The Moorehead patent (U.S. Patent No. 3,766,916)
BD 1006	The Brimhall patent (U.S. Patent No. 5,697,914)
BD 1007	The Enzmann patent (U.S. Patent No. 4,468,224)
BD 1008	Amendment dated Feb. 21, 1997
BD 1009	Final Office Action dated May 12, 1997
BD 1010	The Vaillancourt patent (U.S. Patent No. 4,205,675)
BD 1011	The Moorehead II patent (U.S. Patent No. 4,068,659)
BD 1012	The Fields II patent (U.S. Patent No. 5,088,984)
BD 1013	The American Heritage Dictionary 179-180 (3d ed. 1996)
BD 1014	The Wallace patent (U.S. Patent No. 5,342,316)