Trials@uspto.gov
Tel: 571-272-7822

Paper 10
Entered: October 1, 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY
Petitioner

v.

ONE STOCKDUQ HOLDINGS, LLC
Patent Owner

Case IPR2013-00235
Patent 5,704,914

Before KEVIN F. TURNER, BRIAN J. McNAMARA, and ADAM V. FLOYD *Administrative Patent Judges.*

FLOYD, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a):

> THRESHOLD – The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Becton, Dickinson and Company ("BD" or "Petitioner") filed a Petition ("Pet.") to institute an *inter partes* review of claims 22-26, 28, 29, and 31 (the "challenged claims") of U.S. Patent 5,704,914 (the "'914 patent"). 35 U.S.C. § 311. One StockDuq Holdings, LLC ("One-SD" or "Patent Owner") timely filed a Preliminary Response ("Prelim. Resp."). Generally, One-SD contends that the Petition should be denied as to all challenged claims. We conclude that BD has satisfied its burden under 35 U.S.C. § 314(a) to show that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims.

The '914 patent has been and is currently involved in district court litigation. On December 3, 2012, One-SD filed a complaint against BD alleging infringement of the '914 patent. *One StockDuq Holdings, LLC*, 2:12-cv-03037 (W.D. Tenn.). Pet. 1; Prelim. Resp. 5-6. That case is ongoing.

A. The '914 Patent (Ex. 1001)

The '914 patent generally relates to the field of catheter assemblies used to place a catheter into a liquid-containing region such as a blood vessel (*i.e.*, intravenous or IV). Ex. 1001 ('914 patent), col. 1, ll. 1-8. As described in the Background of the Invention, catheter assemblies have long been known. *Id.*, col. 1, ll. 14-16. However, the inventors of the '914 patent perceived problems with the prior art catheter assemblies. Namely, some of the prior art assemblies allowed the needle to be exposed during the catheterization process creating the possibility of an accidental needle stick. *Id.*, col. 1, ll. 45-50. Another perceived issue was the possibility of blood leakage from the needle during the catheterization process or as a result of blood flashback, raising contamination concerns. *Id.*, col. 1, l. 50 – col. 2, l. 3.

The inventors have attempted to resolve these issues and other perceived shortcomings with the catheter assembly depicted in Figure 4 of the '914 patent—a colorized and labeled version of which is depicted below.[1]

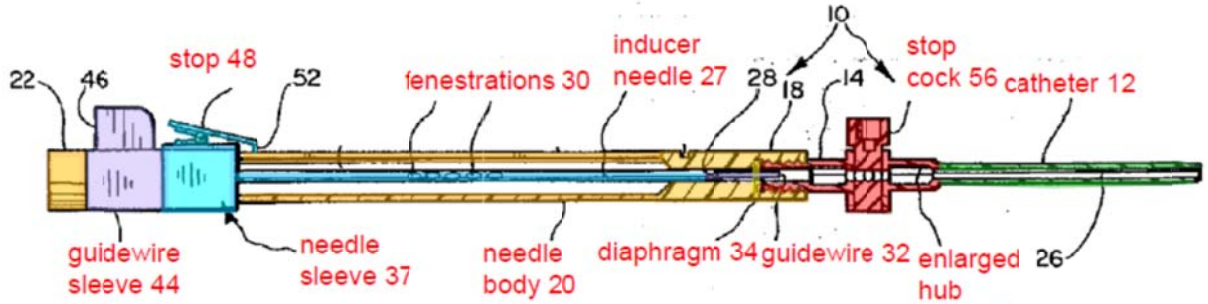


FIG. 4

[1] The general descriptions provided herein of the '914 patent and prior art catheter assemblies are not intended to be complete, but rather to provide the reader with a high-level understanding of the preferred embodiments. In addition, it should not be inferred from the following discussion that the claims are limited to the preferred embodiment of the '914 patent described.

The catheter assembly is made up of three primary portions—catheter 12 (green), cather hub 14 (red), and needle body 20 (orange). In use, stop 48 is released and needle 27 is advanced via needle sleeve 37. As needle 27 is advanced, it passes through diaphragm 34 (yellow) which may contain a deformable slit. Needle 27 is inserted in the patient and blood flashback can be observed in enlarged hub lumen 24 as needle 27 contains fenestrations 30 which allow blood flowing up needle cannula 26 to fill enlarged hub lumen 24. Diaphragm 34 prevents the blood from flowing past catheter hub lumen 14. Next, guidewire 32 is advanced via guidewire sleeve 44 as depicted in Figure 3 of the '914 patent (a colorized and labeled version of which is included below).

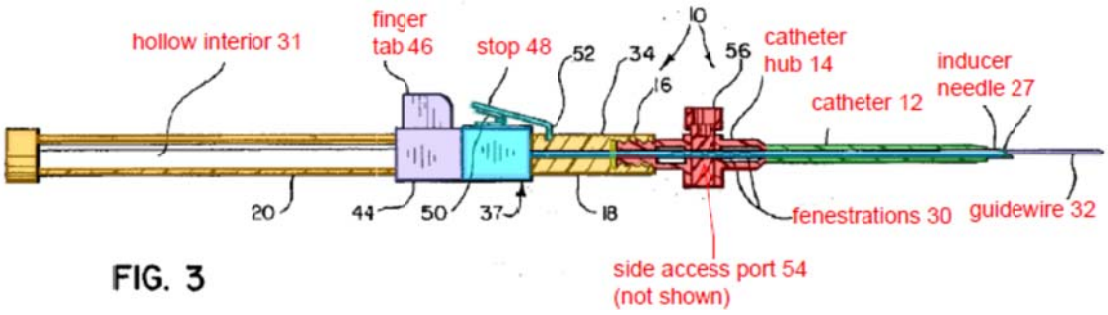


FIG. 3

If there is no resistance on guidewire 32, catheter 12 is inserted into the patient while simultaneously holding down stop 48 so that, as catheter 12 is being inserted, needle 27 and guidewire 32 do not advance into the patient any further. Needle 27 and guidewire 32 are then fully retracted, and needle body 20 is removed, leaving catheter 12 and catheter hub lumen 14 attached to the patient. A side access port 54 may also be provided, but is not visible in Figure 3, as the port is perpendicular to page. *See* Ex. 1001 ('914 patent), col. 5, l. 65 – col. 6, l. 49.

B. Exemplary Claim

Claims 22 and 31 are the independent claims of the '914 patent at issue. Claim 31 is exemplary of the claims and recites:

> 31. A catheter assembly comprising:
>
> a flexible catheter defining a passageway which extends between open proximal and distal ends[;]
>
> 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[;]
>
> 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[;]
>
> a needle attachment body removably connected to said hub[;] and
>
> 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 a 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.

C. The Prior Art

BD relies upon the following prior art references:

U.S. Patent 5,697,914 (Ex. 1006) ("Brimhall"), issued Dec. 16, 1997;

U.S. Patent 4,468,224 (Ex. 1007) ("Enzmann"), issued Aug. 28, 1984;

U.S. Patent 5,098,395 (Ex. 1002) ("Fields"), issued Mar. 24, 1992;

U.S. Patent 5,088,984 (Ex. 1012) ("Fields II"), issued Feb. 18, 1992;

U.S. Patent 3,766,916 (Ex. 1005) ("Moorehead"), issued Oct. 23, 1973;

U.S. Patent 4,068,659 (Ex.1011) ("Moorehead II"), issued Jan. 17, 1978;

U.S. Patent 3,399,674 (Ex. 1003) ("Pannier"), issued Sept. 3, 1968;

U.S. Patent 4,205,675 (Ex. 1010) ("Vaillancourt"), issued Jun. 3, 1980; and

U.S. Patent 5,342,316 (Ex. 1014) ("Wallace"), issued Aug. 30, 1994. [2]

D. Evidence

Additionally, BD relies upon the following evidence:

The declaration of Thomas Vesely, M.D. (Ex. 1004) ("Vesely Decl.");

Response to Office Action dated Feb. 21, 1997 (Ex. 1008);

Final Office Action dated May 21, 1997 (Ex. 1009); and

The American Heritage Dictionary (3d ed. 1996) definition of "between," pp. 179-180 (Ex. 1013).

E. The Asserted Grounds

BD challenges claims 22-26, 28, 29, and 31 as unpatentable under 35 U.S.C. §§102 and/or 103. The specific grounds asserted by BD are summarized in the following table (Pet. 15-60):

[2] While BD included Wallace in its list of prior art relied upon (Pet. 3), none of BD's asserted grounds of unpatentability included Wallace.

Reference[s]	Basis	Claims challenged
Moorehead	§ 102	22, 23, 25, 28, 29, 31
Moorehead and Vaillancourt	§ 103	22, 23, 25, 26, 28, 29, 31
Moorehead, and Fields or Brimhall	§ 103	22, 23, 25, 26, 28, 29, 31
Moorehead or Fields, and Vaillancourt or Moorehead II, and Pannier	§ 103	22, 23, 25, 26, 28, 29, 31[3]
Moorehead and Enzmann	§ 103	24
Moorehead, Vaillancourt, and Enzmann	§ 103	24
Moorehead, Fields or Brimhall, and Enzmann	§ 103	24
Moorehead or Fields, and Vaillancourt or Moorehead II, and Pannier and Enzmann	§ 103	24[4]

[3] With respect to claims 23, 25, 26, 28, and 29, BD argues that the claims are "obvious over the same references applied to claim 22, namely . . . Moorehead in view of Pannier." Pet. 50, 55, 55, 58, and 59, respectively. However, BD did not assert the combination of Moorehead and Pannier with respect to claim 22. We assume BD intended to reference its combination of Moorehead or Fields, and Vaillancourt or Moorehead II, and Pannier.

[4] BD asserts that "claim 24 is obvious over Enzmann in combination with the same references applied to claim 22, namely . . . Moorehead in view of Pannier." Pet. 53. However, BD did not assert Moorehead and Pannier as a combination with respect to claim 22. We assume BD intended to reference its combination of Moorehead or Fields, and Vaillancourt or Moorehead II, and Pannier.

Fields, and Vaillancourt or Moorehead II	§ 103	22, 23, 25, 26, 28, 29, 31
Fields or Brimhall, and Moorehead	§ 103	22, 23, 25, 26, 28, 29, 31
Fields or Brimhall, and Moorehead, and Enzmann	§ 103	24
Brimhall	*§ 102*	*31*
Brimhall, and Vaillancourt or Moorehead	§ 103	31
Brimhall and Fields	*§ 103*	*22, 23, 25, 26, 28, 29*
Brimahall, Fields, and Vaillancourt or Moorehead II	§ 103	22, 23, 25, 26, 28, 29
Brimhall, Fields, and Enzmann	*§ 103*	*24*
Brimhall, Fields, and Vaillancourt or Moorehead II, and Enzmann	§ 103	24

For the reasons described below, we institute an *inter partes* review of claims 22-26, 28, 29, and 31 based on the following grounds: (1) claim 31 as unpatentable under § 102(b) over Brimhall, (2) claims 22, 23, 25, 26, 28, and 29 as unpatentable under § 103(a) over Brimhall and Fields, and (3) claim 24 as unpatentable under 35 U.S.C. § 103(a) over Brimhall, Fields, and Enzmann. The grounds of institution are emphasized in the table above.

F. Claim Construction

As a step in our analysis for determining whether to institute a trial, we determine the meaning of the claims. Consistent with the statute and the

legislative history of the AIA, the Board will interpret claims using the broadest reasonable construction. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012); 37 C.F.R. § 100(b). There is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). By "plain meaning" we refer to the ordinary and customary meaning the term would have to a person of ordinary skill in the art. *In re Translogic Technology, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). However, a claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history. "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Also, we must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

For purposes of this decision, we construe certain claim limitations as follows:

1. Flexible catheter

Both independent claims 22 and 31 recite "a flexible catheter." The '914 patent specification does not shed any light on what "flexible" means as used in conjunction with "catheter." The prosecution history of record is likewise unilluminating.[5] Thus, for the purposes of the petition, we adopt the common and

[5] Response to Office Action dated February 23, 1996 (Ex. 1008) and a Final Office

ordinary meaning of "flexible."

> "Flexible" means "capable of bending easily without breaking."
> Oxford on-line dictionary (http://oxforddictionaries.com/us/definition/american_ english/flexible).

2. Flexible resilient diaphragm

Both independent claims 22 and 31 recite "a flexible, resilient diaphragm." A diaphragm is "a thin sheet of material forming a partition." Oxford on-line dictionary (http://oxforddictionaries.com/us/definition/american_english/diaphragm). This definition is consistent with the Specification which depicts the "diaphragm" 34 as a thin partition. *See, e.g.,* '914 patent, Fig. 4. One-SD's proposed construction defines "a diaphragm" as "a seal."[6] Pet. 6. While the diaphragm disclosed in the '914 patent does serve as a seal, we do not believe that the purpose forms a part of the definition of "diaphragm." Rather, the purpose is recited separately in both independent claims. Ex. 1001 ('914 patent), claim 22 ("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"); and claim 31 ("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

---

Action, dated May 12, 1997 (Ex. 1009) are the only portions of the prosecution history which have been introduced into the official record.

[6] BD did not offer any claim constructions nor did it contest those offered by One-SD.

and projecting into said hub lumen, from flowing through said diaphragm beyond said hub"). Thus, defining "a diaphragm" as "a seal" would introduce a redundancy into the claims. Further, the common and ordinary definition of "diaphragm" is "a thin sheet of material forming a partition" which does not require a seal per se.

In addition, the diaphragm is recited as being "flexible" and "resilient." Oxford's On-line Dictionary defines "flexible" as "capable of bending easily without breaking," whereas, "resilient" is defined as "able to recoil or spring back into shape after bending, stretching, or being compressed." Oxford On-Line Dictionary (http://oxforddictionaries.com/us/definition/american_ english/flexible) and (http://oxforddictionaries.com/us/definition/american_ english/resilient). These definitions are consistent with the '914 patent, which discloses that the diaphragm withstands being punctured by introducer needle 27 and remain liquid tight when the needle is retracted. Ex. 1001 ('914 patent), col. 4, ll. 24-54. Claim 1 recites, "a flexible[,] resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle" which is consistent with the definition of "flexible." *See also* Ex. 1001 ('914 patent), claim 34. Thus, the diaphragm is "flexible" enough to be penetrated by an introducer needle and "resilient" enough to self-seal, once the needle is withdrawn. Therefore, for purposes of the petition we apply the following definition:

> "Flexible[,] resilient diaphragm" means a thin sheet of material forming a partition which is capable of bending or being penetrated by a needle easily without breaking and able to spring back into shape after being penetrated.

3. Between

Independent claim 22 recites that the "diaphragm [is] attached between [needle attachment] body and a proximal end of said hub proximal to said side access port." In contrast, claim 31 recites that the "diaphragm [is] attached to said hub." One-SD's construction of "between" (i.e., "in a space that separates the needle attachment body and a proximal end of the catheter hub") does not address the issue squarely. Pet. 7 (*citing* Ex. 1013 (The American Heritage Dictionary, pp. 179-80 (3d ed. 1996)). The issue is whether "between" the needle attachment body and hub requires the entirety of needle body 20 and the entirety of the hub 14 be located on opposite sides of diaphragm 34. For example, is diaphragm 34, in Figure 3 of the '914 patent, "between" hub 14 and needle body 20?

The Specification does not define "between" explicitly or implicitly. The Specification does state that the "diaphragm 34 may be removably disposed in the hub 14," or "may be contained in a housing . . . removably attached to the hub 14." Ex. 1001 ('914 patent), col. 4, ll. 35-41 (emphasis removed). However, it is not clear if one or both of these diaphragm locations is considered "between" the hub and needle body. Likewise, nothing in the prosecution history of record speaks to the definition of "between." Thus, for purposes of the petition, we use the broadest common and ordinary meaning of "between" which is "at, into, or across the space separating (two objects or regions)." Oxford On-Line Dictionary (http://oxforddictionaries. com/us/definition/american_english/between). Under this definition, diaphragm 34, in Figure 3 of the '914 patent, is "between" hub 14 and needle body 20, as it is at, into, or across the space separating the hub and body.

"Between" means "at, into, or across the space separating (two objects or regions)."

II. ANALYSIS

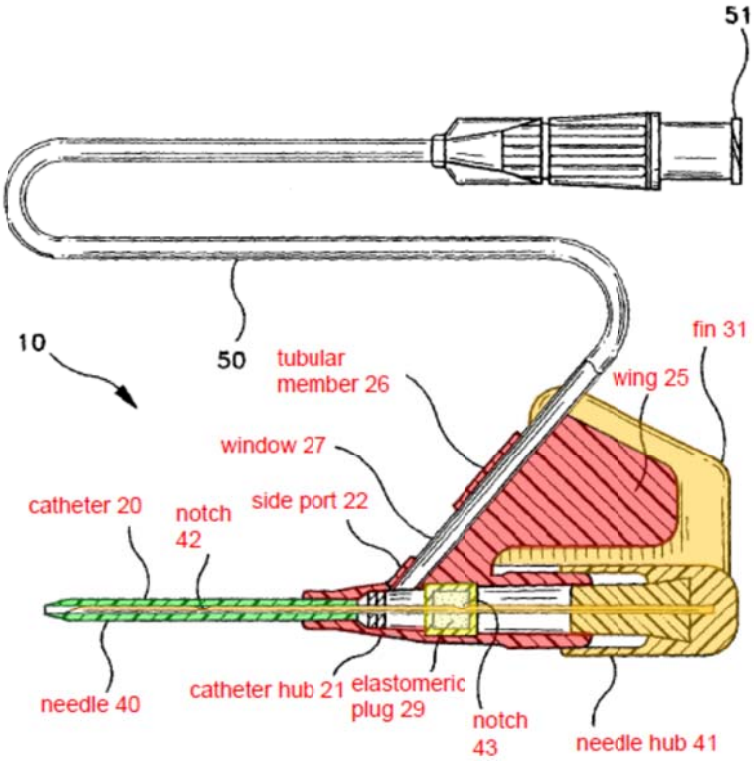
We turn now to Petitioner's asserted grounds of unpatentability and Patent Owner's arguments in its preliminary response to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a).

A. Grounds Based on Brimhall

1. Brimhall (Ex. 1006)—Claim 31

Brimhall is a U.S. patent which was filed on March 16, 1995 and issued December 16, 1997. Brimhall describes a catheter assembly used to place an intravenous ("IV") catheter into a patient. Figure 4 of Brimhall has been colorized and labeled and is depicted below.

FIG–4



The Brimhall catheter assembly has four primary parts: catheter 20 (green), catheter hub 21 (red), needle hub 41 (orange), and side port 22 with extension tube 50. In use, needle 40 is advanced through elastomeric plug 29 via needle hub 41. Fin 31 then is rotated 90 degrees relative to wing 25. *See* Ex. 1006 (Brimhall), Fig. 3. Needle 40 then is inserted into the patient and blood flashback may be observed at notch 42 if the catheter is clear and/or window 27, as notch 43 allows blood to flow from the cannula of needle 40 into catheter hub 21. Note that elastomeric plug 29 prevents blood from flowing past catheter hub 21. Catheter 20 is then inserted into the patient, while simultaneously holding the fin in place to prevent needle 40 from advancing further into the patient. The needle is retracted via needle hub 41 and removed leaving catheter 20 and catheter hub 21 attached to

the patient. Side port 22 may be used to attach an IV fluid supply. Ex. 1006 (Brimhall), col. 3, l. 59 – col. 4, l. 44.

2. Alleged anticipation of claim 31

Petitioner, BD, asserts that claim 31 is anticipated by Brimhall. Pet. 27-29. Patent Owner, One-SD, argues that Brimhall does not disclose the recited "flexible, resilient diaphragm." Prelim. Resp. 18-19. In its claim chart of Brimhall, BD identifies column 3, lines 22 to 25 and lines 52 to 55 as well as figures 2 and 4 as disclosing a flexible resilient diaphragm. Pet. 29. These passages disclose elastomeric (e.g., silicone) plug 29 located at the proximal end of catheter hub 21 to prevent liquid flow past access port 22. Introducer needle 40 when placed in its operative position, as depicted in figure 2, extends through the lumen of catheter hub 21 and through the passageway of catheter 20. It should be noted that elastomeric plug 29 through which the needle penetrates is described as being filled with silicone gel to prevent fluid leakage. Ex. 1006 (Brimhall), *see, e.g.*, Fig. 4 and col. 4, ll. 38-44. BD notes that, while Brimhall does not explicitly state that catheter 20 is "flexible," it does state that "[n]eedle 40 provides column strength to catheter 20 as it is advanced into the vein." Pet. 30; Ex. 1006 (Brimhall), col. 4, ll. 34-36 (emphasis removed).

One-SD also argues that Brimhall does not disclose an "introducer needle defining at least one fenestration" as recited in claim 31. Prelim. Resp. 19. In its claim chart, BD cites the following portions of the Brimhall patent as disclosing an introducer needle including at least one fenestration: column 3, line 49 to column 4, line 1; column 4, lines 20-28 and lines 39 to 42; and figure 2. Pet. 29. The second cited passage explains that introducer needle 40 contains two notches (i.e., fenestrations) 42, 43 both of which communicate with the cannula of

introducer needle 40 when in operative position (depicted in figure 2). Ex. 1006 (Brimhall), col. 4, ll. 20-28. At least one notch 43 is located on a central portion of needle 40. Ex. 1006 (Brimhall), Fig. 2.

We find reasonable BD's contentions that Brimhall discloses each limitation of claim 31, including the flexible resilient diaphragm and an introducer needle with at least one fenestration. We, thus, conclude that there is a reasonable likelihood that BD will prevail on proving anticipation of claim 31 by Brimhall.

B. Obviousness Grounds Based on Brimhall Combinations—Claims 22, 23, 25, 26, 28, and 29

BD argues that independent claim 22 is very similar to independent claim 31, but that notes claim 22 adds "a side access port" which BD argues is disclosed in Brimhall as side port 22. Pet. 38-39. In addition, BD points out that in claim 31 the "flexible resilient diaphragm" is "attached to said hub," whereas, in claim 22 it is "attached between [the needle attachment] body and a proximal end of said hub proximal to said side access port." Pet. 40. BD relies upon the disclosure of Fields for the disclosure of the diaphragm being "between" the body and hub. Pet. 41.[7]

1. Fields (Ex. 1002)

The catheter assembly of Fields has three primary portions: catheter 34 (green), second connection member 28 (red), and first connection member 12 (orange). A colorized and labeled version of figure 1 from Fields is included

[7] Given our initial construction of "between" (*i.e.*, "at, into, or across the space separating (two objects or regions)" the plug 29 may be "between" the needle hub 41 and catheter hub 21.

below.

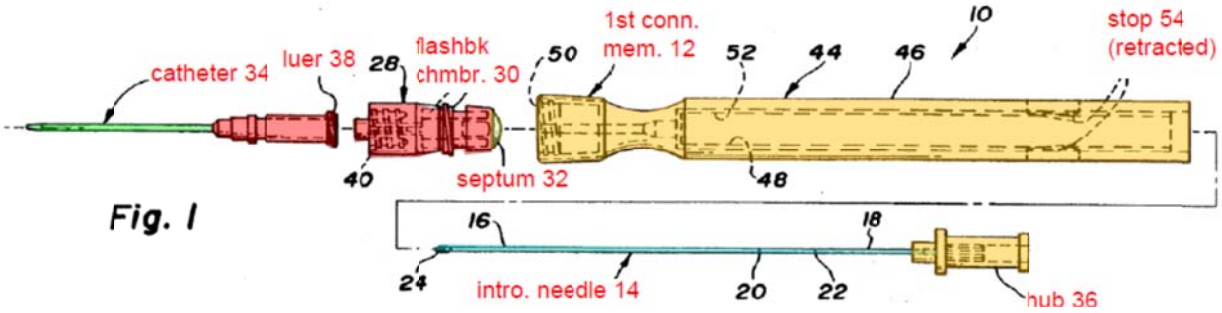


Fig. 1

In use, stop 54 is released and needle 14 advanced via needle hub 36. As needle 14 is advanced, it passes through septum 30 (yellow). The needle is inserted in the patient and blood flashback can be observed in flashback chamber 30, as needle 14 contains openings 20, 22, which allow blood flowing up the needle cannula to fill the flashback chamber. Note that septum 32 prevents the blood from flowing past second connection member 28. The catheter is then inserted into the patient and needle 14 retracted. First and second connection members 12, 28 are removed, leaving catheter 34 attached to the patient. While Fields does not directly disclose a side access port, it does incorporate Fields II by reference. Ex. 1002 (Fields), col. 3, ll. 24-28. As depicted in figure 3, Fields II does disclose a side access port 44. Ex. 1012 (Fields II).

2. Alleged Obviousness of Claims 22, 23, 25, 26, 28, and 29 in view of Brimhall and Fields

a. Claim 22

BD argues that Fields discloses flexible, resilient septum 32 attached between first connector member/needle attachment body 12 and a proximal end of second connector member/hub 28. Pet. 41; *see* Ex. 1002 (Fields), Fig. 1. BD further argues that it would have been obvious to attach plug 29 of Brimhall

between hub 21 and needle hub/needle attachment body 41 as shown in Fields and that doing so would still allow plug 29 to be penetrated by needle 40 and still prevent fluid spillage. Pet. 42. In essence, BD argues the precise location of the diaphragm/plug is merely a matter of design choice.

One-SD argues that BD has made "no showing that Fields describes or suggests a catheter assembly with 'a flexible[,] resilient diaphragm . . . attached to [the] 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 . . . from flowing through said diaphragm beyond said hub.'" Prelim. Resp. 22. One-SD does not explain what portion(s) of the limitation are not disclosed in Fields. *Id.* We find BD's contentions that Brimhall and Fields disclose the limitations of claim 22, including the flexible, resilient diaphragm, to be reasonable. We conclude that there is a reasonable likelihood that BD will prevail on proving unpatentability of claim 22 over Brimhall and Fields.

b. Claim 23

With respect to claim 23, which further limits claim 22 by reciting that the "side access port is formed on said hub," BD argues that the limitation is disclosed in Brimhall as side port 22 is formed on hub 21. Pet. 50; *see* Ex. 1006 (Brimhall), Fig. 1. One-SD does not contest BD's argument, which we find to be reasonable. Prelim. Resp. 17-21. We conclude that there is a reasonable likelihood that BD will prevail on proving unpatentability of claim 23 over Brimhall and Fields.

c. Claims 25 and 26

With respect to claims 25 and 26, each of which depends from claim 22, claim 25 further limits claim 22 by reciting that the "hub is at least partially transparent," whereas claim 26 further limits claim 22 by reciting that the "hub is at least partially translucent." BD argues that Brimhall discloses a transparent or

translucent window 27 to observe flash back. Pet. 56; *see* Ex. 1006 (Brimhall), Fig. 1; col 4, ll. 21-23. BD argues that it would have been obvious to move flashback window 27 from side port 22 to hub 21, as doing so would not interfere with the window's current purpose of allowing the visualization of blood flow and the precise location of the window is merely a matter of design choice. Pet. 55. BD also argues that Fields discloses flashback chamber 30, which is part of second connector member/hub 28. One-SD does not contest BD's argument which we find to be reasonable. Prelim. Resp. 17-21. We conclude that there is a reasonable likelihood that BD will prevail on proving unpatentability of claims 25 and 26 over Brimhall and Fields.

d. Claim 28

With respect to claim 28, which depends from and further limits claim 22 by reciting, "needle attachment body is removably connected to said hub," BD argues the limitation is disclosed in Brimhall. Pet. 57-58. Specifically, BD argues that in Brimhall, once catheter 20 is in the patient, needle hub/needle attachment body 41 is removed from catheter 20 and hub 21. Pet. 58 (*citing* Ex. 1006 (Brimhall), col. 4:35-37). One-SD does not contest BD's argument, which we find to be reasonable. Prelim. Resp. 17-21. We conclude that, there is a reasonable likelihood that BD will prevail on proving unpatentability of claim 28 over Brimhall and Fields.

e. Claim 29

With respect to claim 29, which further limits claim 22 by reciting that the "diaphragm is directly attached to said catheter hub," BD argues that the limitation is disclosed in Brimhall. Pet. 59. Specifically, BD notes that in figures 2 and 4, diaphragm 29 is located inside and attached to catheter hub 21. Pet. 59. One-SD does not contest BD's argument, which we find to be reasonable. Prelim. Resp.

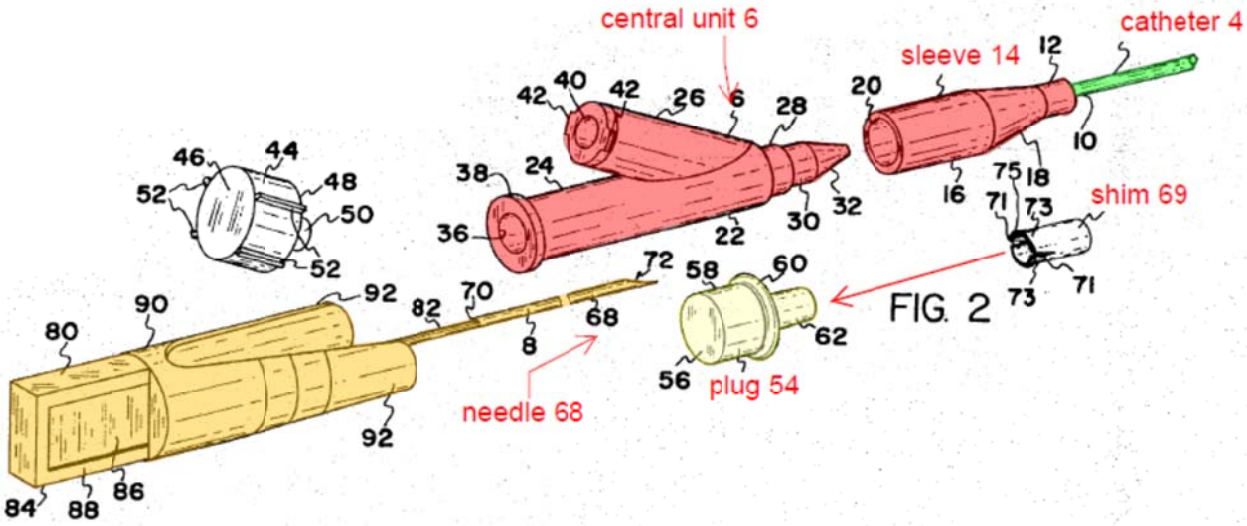
17-21. We conclude that there is a reasonable likelihood that BD will prevail on proving unpatentability of claim 29 over Brimhall and Fields.

3. Alleged Obviousness of claim 24 over Brimhall, Fields, and Enzmann

Claim 24 further limits claim 22 by reciting, "further comprising a multi-position stopcock 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." BD alleges that Enzmann discloses stopcock 75 for selectively closing access ports 76, 77. Pet. 52; (*citing* Ex. 1007 (Enzmann), Fig. 8). BD further argues that it would have been obvious to use a stopcock like that disclosed in Enzmann to control the flow of fluid through side port 22 of Brimhall. Pet. 53. One-SD does not contest BD's argument, which we find to be reasonable. Prelim. Resp. 17-21. We conclude that there is a reasonable likelihood that BD will prevail on proving unpatentability of claim 24 over Brimhall, Fields, and Enzmann.

C. Remaining Grounds

BD argues several grounds of unpatentability based upon Moorehead as the primary reference. Pet. 15-20, 31-33, 43-45, 47-49. We conclude that there is not a reasonable likelihood that BD will prevail on its alleged grounds of unpatentability which are based on Moorehead. As depicted in Figure 2 of Moorehead (shown below colorized and labeled), the catheter assembly is made up of four primary portions—catheter 4 (green), sleeve 14 (red), central unit 6 (red), and cylindrical shell portion 90 joined to tab member 80 (collectively orange).



In use, needle 68 is pushed through plug 54 (yellow) until it extends beyond the tip of catheter 4. Needle 68 is inserted into the patient and blood flashback can be observed in central unit 6 as needle 68 contains opening 82, which allows blood flowing up the needle cannula to be seen through transparent central unit 6. Plug 54 in conjunction with shim 69 prevents the blood from flowing past central unit 6. The catheter then is inserted into the patient. It is unclear whether cylindrical shell portion 90 joined with tab member 80 is removed leaving catheter 4, sleeve 14, and central unit 6 attached to the patient or whether the entirety of the catheter assembly remains attached to the patient. Side access port 40 is provided for attaching a bag of IV fluid. *See* Ex. 1005 (Moorehead), col. 3, l. 43 – col. 4, l. 2.

BD argues that 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." Pet. 16 (*citing* Ex. 1005 (Moorehead), col. 2, ll. 13-17 and Ex. 1004 (Vesely Decl.) ¶ 36). The cite to Moorehead does include PTFE (commonly referred to by the trade name "Teflon"). Ex. 1005 (Moorehead), col. 2, ll. 13-17 ("catheter tube **4** is preferably formed of a suitable transparent or translucent

radiopaque synthetic resin, such as polyvinyl, polyprophylene, polyethylene, polytetrafluorethylene, etc."). However, Moorehead does not provide any indication that PTFE or catheter 4 is flexible. Dr. Vesely's statement that "[p]olytetrafluorethylene (PTFE) is commonly known in the medical community as a flexible material," is not specific enough. Ex. 1004 (Vesely Decl.) ¶ 36). To show inherency, BD would need to prove that a catheter made of PTFE would *necessarily* be flexible. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (*quoting Continental Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268 (Fed. Cir. 1991)) ("To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'") "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (*citing Hansgirg v. Kemmer*, 102 F.2d 212, 214 (1939)). While Dr. Vesely states that PTFE is "commonly known in the medical community as flexible material," he does not state that PTFE is necessarily or always used in flexible form in the medical community.

BD makes alternative arguments of unpatentability in which it combines Moorehead with the flexible catheter disclosed in Vaillancourt. Pet. 19-20 (*citing* Ex. 1010 (Vaillancourt), col. 6, ll. 46-51; col. 2, ll. 10-11; and col. 1, l. 32). However, Vaillancourt criticizes leaving the needle in place while positioning the flexible catheter as the flexible catheter may be cut or severed as it passes over the sharp point of the needle. Ex. 1010 (Vaillancourt), col. 1, ll. 22-33. BD's proposed combination would result in Vaillancourt's flexible catheter being positioned, while needle 68 of Moorehead is in the patient. The flexible catheter would have to pass over the sharp point of needle 68.

BD also argues that self-sealing wall 67 of plug 54 of Moorehead constitutes a flexible, resilient diaphragm as recited in the challenged claims. Pet. 17. However, claim 22 recites that the diaphragm is for "preventing the flow of a liquid through said hub lumen past said side access." Similarly, claim 31 recites the diaphragm is attached to the 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 flowing through said diaphragm beyond said hub." It is not clear that wall 67 of plug 54 prevents flow of liquid (e.g., blood) past the hub lumen. Moorehead discloses using shim 69 in conjunction with plug 54 in an effort to block blood flow. Ex. 1005 (Moorehead), col. 3, ll. 6-15; col. 3, ll. 58-68; Fig. 4 and 5. We conclude that BD was not persuasive in demonstrating a reasonable likelihood that it will prevail on proving: anticipation of claims 22, 23, 25, 28, 29, and 31 by Moorehead; or unpatentability of claims 22, 23, 25, 26, 28, 29, and 31 over Moorehead and Vaillancourt. As Enzmann was not argued to disclose a flexible catheter or a liquid tight diaphragm, we likewise conclude that BD was not persuasive in demonstrating a reasonable likelihood that it will prevail on proving unpatentability of claim 24 by Moorehead and Enzmann. Pet. 52-54.

Furthermore, BD did not argue that the disclosures of Moorehead II, Pannier, Fields, or Brimhall[8] contribute to the disclosure of Moorehead with respect to a flexible catheter or a liquid tight diaphragm. Pet. 43-44, 47-49. Accordingly, for the reasons set forth above, we likewise conclude that BD does not present persuasive evidence establishing a reasonable likelihood that BD will

[8] While BD did argue that Fields and Brimhall did disclose flexible catheters and liquid tight diaphragms, it did not do so in the context of combining these references with Moorehead to make up for the shortcomings therein. *See* Pet. 34-38 (discussing Fields), 38-41 (discussing Brimhall).

prevail on proving unpatentability of: claims 22, 23, 25, 26, 28, 29, and 31 by Moorehead, Vaillancourt or Moorehead II, and Pannier; claims 22 and 31 by Moorehead and Field or Brimhall; claim 24 by Moorehead, Vaillancourt, and Enzmann; or claim 24 by Moorehead, Vaillancourt or Moorehead II, and Pannier.

As should be evident from the discussions above regarding Brimhall and Fields, the two references are very similar with respect to the limitations in the challenged claims. Thus, the remaining grounds of unpatentability proposed by Petitioner are redundant to those grounds discussed above. We do not authorize *inter partes* review on those redundant grounds.

III. CONCLUSION

Petitioner has demonstrated that there is a reasonable likelihood of prevailing on its challenge to the patentability of the claims 22-26, 28, and 29 of the '916 patent based on the following grounds:

Claim 31 as anticipated under § 102(b) by Brimhall;

Claims 22, 23, 25, 26, 28, and 29 as unpatentable under § 103(a) over Brimhall and Fields; and

Claim 24 as unpatentable under 35 U.S.C. § 103(a) over Brimhall, Fields, and Enzmann.

The Board has not made a final determination on the patentability of the challenged claims.

IV. ORDER

For the reasons given, it is:

ORDERED that the Petition is granted as to claims 22-26, 28, 29, and 31.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '916 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the grounds listed in the Conclusion. No other grounds are authorized.

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2 PM Eastern Time on October 29, 2013. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

PETITIONER:

David Cavanaugh
Owen Allen
WILMER CUTLER PICKERING HALE AND DORR LLP
david.cavanaugh@wilmerhale.com
owen.allen@wilmerhale.com

PATENT OWNER:

William C. Ferrell, Jr.
STITES & HARBISON, PLLC
wferrell@stites.com