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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]

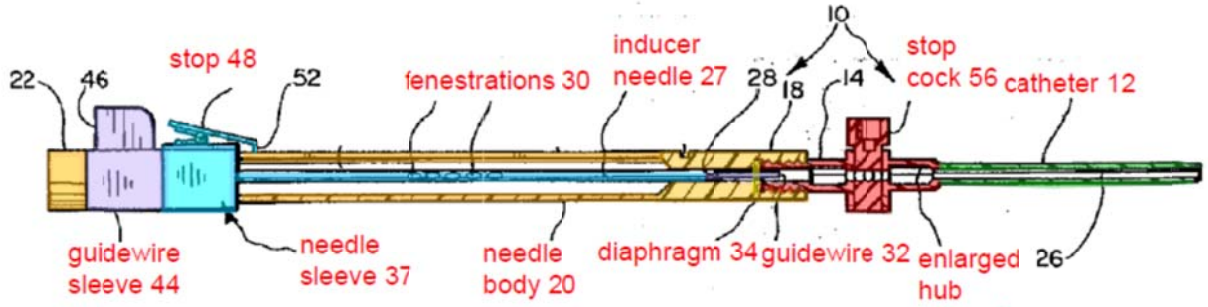

FIG. 4

[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).

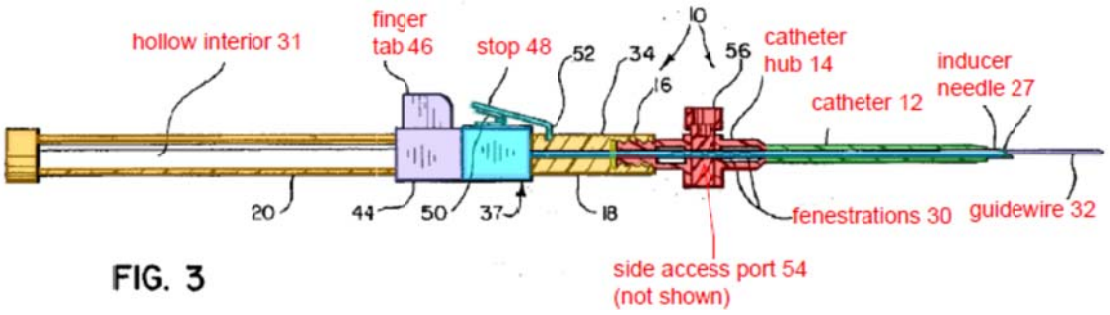

FIG. 3

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.

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