Paper No. 8 Entered: December 15, 2017

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY, Petitioner,

v.

B. BRAUN MELSUNGEN AG, Patent Owner.

> Case IPR2017-01585 Patent 8,337,463 B2

Before SCOTT A. DANIELS, MICHAEL L. WOODS, and ROBERT L. KINDER, *Administrative Patent Judges*.

DANIELS, Administrative Patent Judge.

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

## I. INTRODUCTION

## A. Background

Becton, Dickinson and Company ("Petitioner") filed a Petition requesting *inter partes* review of claims 1, 2, 10, 12, 25, and 28 of U.S. Patent No. 8,337,463 B2 ("the '463 patent"). Paper 3, ("Pet."). B. Braun Melsungen AG ("Patent Owner") filed a Preliminary Response contending that the Petition should be denied as to all challenged claims. Paper 7, ("Prelim. Resp.").

We have jurisdiction under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "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." Having considered the arguments and the evidence presented, for the reasons described below, we do not institute an *inter partes* review of any of the challenged claims.

### B. Additional Proceedings

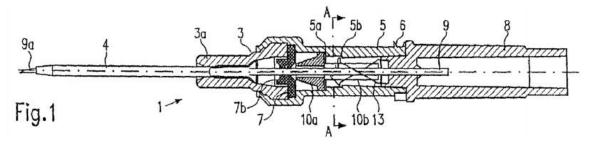
Petitioner represents that the '463 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1. Petitioner also represents that petitions for *inter partes* review were also filed challenging related patents US. Patent Nos.: 8,328,762; 8,333,735; 8,540,728; 9,149,626; 8,597,249; 8,460,247; and IPR2017-01585 Patent 8,337,463 B2

9,370,641. *Id.* Below is a chart that associates the *inter partes* reviews with each patent:

IPR Number	Patent Number
IPR2017-01583	8,333,735
IPR2017-01584	8,540,728
IPR2017-01585	8,337,463
IPR2017-01586	8,328,762
IPR2017-01587	9,149,626
IPR2017-01588	8,460,247
IPR2017-01589	8,597,249
IPR2017-01590	9,370,641

## C. The '463 Patent (Ex. 1001)

The '463 patent, titled "Catheter Insertion Device," purports to prevent "an outflow of blood from the catheter . . . after removal of the hollow needle with [a] needle guard element." Ex. 1001, 1:33–34. Figure 1 of the '463 patent's catheter insertion device is reproduced below:



According to the '463 patent, Figure 1 depicts catheter insertion device 1 with catheter 4, needle hub 8, to which hollow needle 9 is fixed and which needle 9 passes through valve disc 7 and extends through catheter 4. Ex. 1001, 2:8–9, 19–22. Between needle hub 8 and valve disc 7 is valve actuating element 10, which has a truncated cone-shaped section 10a, which serves to open valve disc 7. *Id.* at 2:20–24. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:27–29. Needle guard element 13 serves to cover needle tip 9a upon withdrawal of needle 9 from the catheter hub, thereby "completely protecting and blocking it," as shown in Figure 2. *See id.* at 2:31–39.

To illustrate the removal of needle 9 from catheter hub 2, we reproduce Figure 2, below:

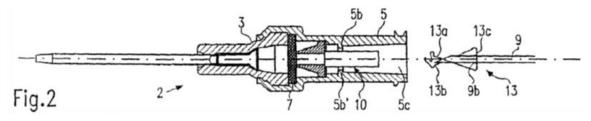


Figure 2, above, depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:57–58, 2:33–38. As shown, when needle guard element/spring clip 13 is removed from the catheter hub along with needle 9, the spring clip's spring arms 13a, 13b cover the needle's tip. *Id.* at 2:38–41. Figure 2 depicts also valve disc 7—which is elastic—as closing the through-hole from which needle 9 is removed to prevent blood flow from exiting the catheter. *Id.* at 2:41–44.

## D. Illustrative Claim

Of the challenged claims, claims 1, 10, and 25 are independent. Each of dependent claims 2, 12, and 28 depend directly from respective independent claims 1, 10, and 25. Claim 1 illustrates the claimed subject matter and is reproduced below:

- 1. A catheter insertion device comprising:
- a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;
- a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;
- a valve sized and shaped to obstruct fluid flow through the catheter hub comprising a wall surface comprising a slit positioned inside the interior cavity of the catheter hub and abutting a shoulder in the interior cavity of the
- catheter hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;
- a valve actuating element slidingly disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit of the valve and *at least two plunger elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough; the two plunger elements structured to transfer a distally directed force to the nose section to push the valve to open the slit;*
- a needle protective device spaced from the needle tip in a ready position and movable relative to the needle tip to a protective position, at least in part, distally of the needle tip to prevent unintended needle sticks.

Ex. 1001, 5:2–30 (emphasis added).

E. The Alleged Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable on the

following specific grounds.1

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<sup>&</sup>lt;sup>1</sup> Petitioner supports its challenge with a Declaration of Jack Griffis, III, (Ex. 1002), and in its Preliminary Response, Patent Owner relies upon a Declaration of Richard Meyst (Ex. 2001). *See infra*.

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