## Becton, Dickinson and Company v. One StockDuq Holdings, LLC: Final Written Decision IPR2013-00235

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Takeaway: New persuasive evidence is likely required for the Board to modify the claim construction adopted in its Decision to Institute.

In its <u>Final Written Decision</u>, the Board found that claims 22-26, 28, 29, and 31 of the '914 patent (the only challenged claims) were unpatentable. The '914 patent relates generally 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).

The Board began with claim construction, stating that the terms are construed according to their broadest reasonable interpretation in light of the patent specification. The Board discussed the construction of three terms: flexible catheter, flexible resilient diaphragm, and between. First, the Board noted that the '914 patent Specification did not shed any light on what "flexible" means in conjunction with "catheter." Also, neither party directed the Board to any statements in the prosecution history to define the term. Thus, the Board adopted in its Decision to Institute the common and ordinary meaning of "flexible" given in the Oxford dictionary, which is "capable of bending easily without breaking." Neither party contested the construction, so the Board adopted the same definition for purposes of the Final Written Decision.

The Board similarly construed the term "flexible resilient diaphragm" using definitions from the Oxford dictionary, because those definitions were consistent with the Specification in its Decision to Institute. Petitioner argued that "diaphragm" should not be limited to "a thin sheet of material forming a partition," as defined in the Oxford dictionary, because the Specification does not explicitly limit the term to a particular thickness. However, the Board did not depart from the construction it adopted in its Decision to Institute, because Petitioner had provided no new evidence to support a different construction.

The term "between" required construction to determine if "between" the needle attachment body and hub requires the entirety of the needle body and the entirety of hub to be located on opposite sides of diaphragm. Again the Specification did not explicitly or implicitly define "between," and the term was not discussed in the prosecution history. Therefore, the Board used the broadest common and ordinary meaning of "between," which is "at, into, or across the space separating (two objects or regions)." The Board then looked at the first ground of unpatentability: anticipation of claim 31 by Brimhall. Patent Owner only argued that Brimhall failed to disclose the recited "flexible resilient diaphragm." In its claim chart, Petitioner identified passages of Brimhall that disclosed an elastomeric plug located at the proximal end of catheter hub to prevent liquid flow past the access port. Patent Owner asserted that the elastomeric plug was not a "diaphragm" because it is not thin and is not "resilient," as it does not spring back into shape. Patent Owner provided evidence in the form of Wallace II allegedly showing that the art recognized a distinction between using a thicker sealing means, such as a plug, and a thin sheet, such as a diaphragm. The Board agreed with Petitioner that the elastomeric plug of Brimhall is a "flexible, resilient diaphragm," because (1) the plug can be made of an elastomeric material, which would be understood as flexible and resilient; (2) Brimhall is not limited to thick "plugs;" (3) Wallace II did not establish that all plugs are thicker than disphragms and another reference explained that "plug" was a generic term covering a broad range of structure; and (4) Brimhall's broad disclosure of plugs, also disclosed specific types of plugs, including diaphragms.

The Board next analyzed whether claims 22-26, 28, and 29 would have been obvious over combinations of other references with Brimhall. Petitioner contended that independent claim 22 is similar to claim 31, and that Brimhall discloses all of the features of claim 22, except for the limitation in claim 22 that the diaphragm is "between" the body and hub. Petitioner relied on Fields for this disclosure.

First, Patent Owner argued that Fields fails to disclose a flexible, resilient diaphragm, because it discloses a "septum." Patent Owner argued that "septum" and "membrane" are both used in Fields, and that since membrane is a thin material, septum must refer to a thick sheet of material, and thus not a diaphragm. The Board agreed with Petitioner that the septum of Fields discloses the "flexible resilient diaphragm" recited in the claims, because (1) the '914 patent uses the terms "diaphragm" and "septum" interchangeably; (2) septum was not excluded from the claim scope during prosecution; (3) Fields II, which was incorporated by reference into Fields, describes the septum as being flexible and resilient in the same manner as how the '914 describes the diaphragm or septum; (4) the drawings in Fields disclose a diaphragm by showing a flexible sheet that is thin relative to the other components of the catheter assembly; and (5) Petitioner's expert's testimony was found by the Board to be credible on this issue.

Patent Owner also argued that there was would have been no reason to substitute a flexible, resilient diagphragm for elastomeric plug of Brimhall or rubber septum of Fields. The Board determined that both the plug and septum were encompassed by the claimed term "flexible, resilient diaphragm." Also, the Board agreed with Petitioner that even if substitution was necessary, the substitution of a septum for a plug would have been merely the substitution of one known element for another known element in the field to obtain a predictable result.

Finally, the Board analyzed whether claim 24 would have been obvious over the combination of Brimhall, Fields, and Enzmann. Patent Owner merely asserted that Enzmann failed to remedy the deficiencies alleged by Patent Owner with regard to the Brimhall and Fields combination. Accordingly, the Board agreed with Petitioner that the addition of a stopcock to control fluid flow on the side port of Brimhall and Fields would have been the combination of familiar elements according to known methods to yield predictable results.

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Paper 30: Final Written Decision Dated: September 25, 2014 Patent 5,704,914 Before: Kevin F. Turner, Brian J. McNamara, and Kevin W. Cherry Written by: Cherry

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