

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NIPRO CORPORATION,  
Petitioner,

v.

NXSTAGE MEDICAL, INC.,  
Patent Owner.

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Case IPR2016-00744  
Patent 8,092,414 B2

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Before SALLY C. MEDLEY, LYNNE E. PETTIGREW, and  
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

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

## I. INTRODUCTION

Nipro Corporation and Nipro Medical Corporation (collectively, “Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–9, 12–16, 19–26, and 28 of U.S. Patent No. 8,092,414 B2 (Ex. 1001, “the ’414 patent”). Paper 1 (“Pet.”). In response, Patent Owner, NxStage Medical Inc., filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We have jurisdiction under 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.”

For the reasons set forth below, we deny institution of an *inter partes* review of the ’414 patent.

### *A. Related Matter*

Petitioner identifies U.S. Patent Applications related to the ’414 patent. Pet. 1. Petitioner does not identify any related federal district court litigation or post-grant proceeding. *Id.*

### *B. The ’414 Patent*

The ’414 patent relates to a pressure pod for measuring blood pressure in an extracorporeal blood circuit. *See, e.g.*, Ex. 1001, 1:6–18, 2:12–14.

Figure 1 of the '414 patent is reproduced below.

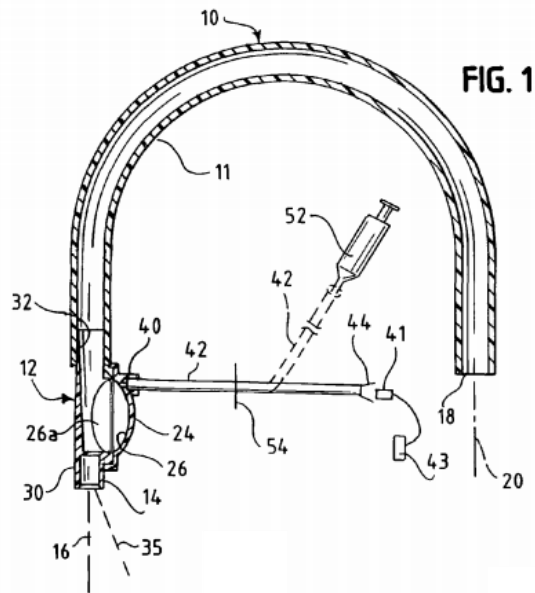


Figure 1 depicts a sectional view of an exemplary tubular blood flow set 10. *Id.* at 7:27–30. As shown in Figure 1, one end of pressure pod 12 is designed to connect to, for example, a dialyzer, via tubing 11, 20. *Id.* at 8:8–10, 19–30. The other end of pressure pod 12 is designed to connect to, for example, a patient, via tubing 16. *Id.* at 8:10–14, 24–30.

Figure 2 of the '414 patent is reproduced below.

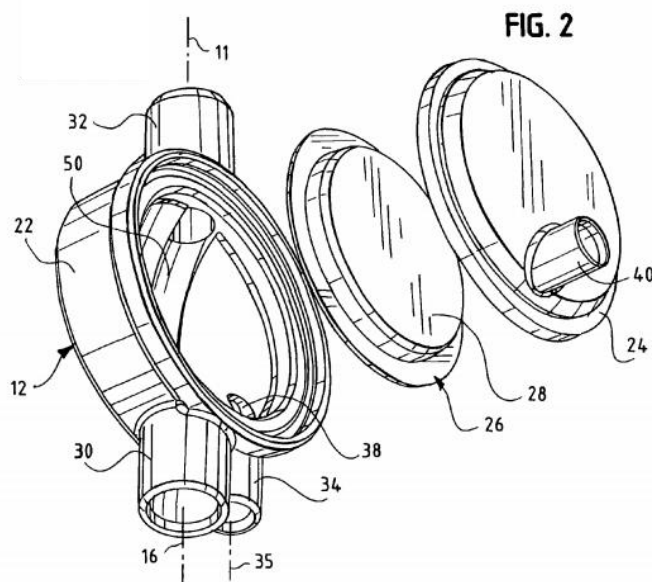


Figure 2 depicts an exploded view of pod 12. *Id.* at 7:31–32. The '414 patent discloses that pressure pod 12 includes lower compartment-defining portion 22, upper compartment-defining portion 24, and diaphragm 26 therebetween. *Id.* at 8:32–34. Lower compartment-defining portion 22 includes blood inlet port 30 and blood outlet port 32, through which blood will flow. *Id.* at 8:36–38. Diaphragm 26 is flexible and “defines a convex, central portion 28 shown to be bulging outwardly from the blood flow portion of the chamber.” *Id.* at 8:34–36. Upper compartment-defining portion 24 includes connection port 40, which connects to pressure tubing 42 and pressure transducer 43, as shown in Figure 1. *Id.* at 8:61–64, 9:5–12.

The '414 patent discloses exemplary operation of the pressure pod as follows:

[O]ne compartment [22] of the pod is part of a fluid flow path, typically blood, through the fluid flow set and the pressure sensing chamber. The other of the compartments [24] is preferably hermetically sealed by a sealed port, until opened for connection with a pressure measuring device. The effect of this is to keep the movable, flexible diaphragm [26] in a desired, initial position prior to said opening. The diaphragm, when the hermetic seal is broken, is capable of moving between a first position and a second, opposed position in which the diaphragm in the first position can bow outwardly from the blood pathway, to maximize blood volume in the chamber, while the diaphragm in the second position can bow inwardly to minimize, but typically not eliminate, blood volume in the chamber.

*Id.* at 3:31–44. In this way, “the air pressure in tube 42 will match the pressure of the blood below diaphragm 26, and that air pressure can be sensed by pressure sensor 43, and reported by an appropriate signal on preferably a moment-by-moment, real time basis.” *Id.* at 9:20–24.

*C. Illustrative Claim*

Claims 1, 13, and 23 are independent claims. Challenged claims 2–9 and 12 depend directly or indirectly from claim 1; challenged claims 14–16 and 19–22 depend directly or indirectly from claim 13; and challenged claims 24–26 and 28 depend directly or indirectly from claim 23.

Claim 1, reproduced below, is illustrative:

1. A tubular blood flow set which comprises a pressure sensing pod defining a chamber, said pod being connected in flow-through relation to blood flow tubing of said set, said set defining a length of *pressure tubing connected at one end with said chamber*, for connection at the other pressure tubing end with a pressure measuring equipment connector with said pod being spaced from said connector; and a flexible diaphragm sealingly mounted within said pod between connections of said blood flow tubing and said pressure tubing, said diaphragm being moveable between first and second positions, the diaphragm in said first position bowing outwardly to substantially maximize volume in said chamber that communicates with said blood flow tubing, the diaphragm in said second position bowing inwardly to substantially minimize but not eliminate the blood volume in said chamber that is inside of said diaphragm, said diaphragm in use being in contact on one side thereof with flowing blood;

*wherein the pressure tubing is flexible and elongate and integrally attached to the chamber to permit the pod to be positioned remotely from the pressure measuring equipment connector and to permit the pod and blood flow tubing set to be connected to blood treatment machines with pressure measuring equipment connectors in various locations of the blood treatment machines.*

Ex. 1001, 14:49–15:5 (emphases added). Independent claims 13 and 23 include language similar to that emphasized above in claim 1. *Id.* at 15:53 (“which [pressure] tubing is integral with said pod”), 16:33 (“the pressure tubing being integral with said pod”).

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