

Filed on behalf of Atrium Medical Corporation
By: David L. Cavanaugh, Reg. No. 36,476
Larissa Park, Reg. No. 59,051
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
Tel: (202) 663-6025
Email: David.Cavanaugh@wilmerhale.com
Larissa.Park@wilmerhale.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATRIUM MEDICAL CORPORATION

Petitioner

v.

DAVOL, INC.

Patent Owner of U.S. Patent No. 7,785,334 to Ford et al.

IPR Trial No. IPR2013-00187

DECLARATION OF THEODORE KARWOSKI

Atrium v. Davol
IPR2013-00187
ATRIUM 1129

Declaration of Theodore Karwoski

I, Theodore Karwoski, declare as follows:

1. My name is Theodore Karwoski.
2. From 1982 through 2013, I worked at Atrium Medical Corporation (“Atrium”), serving variously as Chief Operating Officer, Chief Development Officer, and Senior Vice President of Research and Operations. I am now a consultant to Atrium.
3. Atrium is in the business of making and selling medical devices, including hernia repair devices such as plugs and patches. In the late 1990s, Atrium introduced its Self-Forming Plug, a hernia repair device with three layers of polypropylene mesh including a tissue barrier layer and a center rectangular tab for placement, control of insertion, positioning and attachment. Patented by Atrium in 2000, the Self-Forming Plug was designed to expand into and conform to the shape and space of a hernia defect. Atrium still sells it today.
4. In 2006, Atrium received FDA clearance for, and began to market, its C-QURTM Mesh, a hernia repair device consisting of Atrium’s polypropylene mesh coated with Omega-3 fatty acid (“O3FA”). The C-QURTM Mesh was designed to be a tissue separating layer for open and laparoscopic hernia repair. Atrium still sells it today.

5. In late 2005, Atrium began development of the C-QUR V-PatchTM (“V-PatchTM”). In 2008, Atrium received FDA clearance for, and began to market, the device. Atrium’s V-PatchTM is designed to repair small hernias and other abdominal wall defects. It has an O3FA bioabsorbable coating and is constructed out of two layers of polypropylene mesh that are sewn with, and include, a mesh stabilizing ring. The O3FA bioabsorbable coating is integral to the polypropylene mesh. Building off the success of Atrium’s Self-Forming Plug’s prior art tabs, it also has two extended mesh fixation straps to allow the doctor to position, fixate, and handle the patch.

6. Both patents in these proceedings issued *after* the V-PatchTM was approved for clearance in 2008: the ’334 Patent issued on August 31, 2010 and the ’905 Patent issued on October 5, 2010.

7. Davol, Inc. (“Davol”) competes with Atrium in the hernia repair device market. Since 2002, Davol or its parent company, C.R. Bard, Inc. (“Bard”), have marketed and sold the VentralexTM patch.

8. I understand that, in this proceeding, Davol employee Michael Lee has testified that Atrium copied Davol’s VentralexTM patch. Specifically, I understand that Mr. Lee claims that Atrium’s V-PatchTM is a copy of Davol’s VentralexTM patch.

9. Atrium did not copy Davol's VentralexTM patch, and Atrium's V-PatchTM is not a copy of Davol's VentralexTM patch.

10. As a medical device manufacturer, Atrium naturally wants to develop and sell superior products to compete in the marketplace. In response to requests from doctors for a hernia repair device that would perform better than competitors' products (such as Davol's VentralexTM patch), Atrium developed the V-PatchTM. Beginning in the early 1990s, various plugs and patches were developed to improve repairs made in abdominal wall defects. These implants evolved based upon surgical use and surgeons' feedback on improvements in techniques and design. Initial plugs were found to migrate after insertion due to inadequate anchoring and abdominal wall defect increases and changes, to harden due to poor tissue integration, and to have other inadequacies. Atrium's Self-Forming Plug as marketed (in 1997) and patented (in 2000) built upon prior art evolution and improvements. Through surgical use, Surgeons soon recognized that they could modify the circular plug with tabs of Atrium's Self-Forming Plug to provide a patch, or shield, covering a defect through the abdominal wall. Surgeons then suggested modifications to the Self-Forming Plug's design, and those suggestions were part of the variety of product evolutions and designs that led to the V-PatchTM product.

11. Atrium's V-PatchTM and Davol's VentralexTM patch share certain features, such as a multiple layer structure, use of polypropylene mesh, use of a barrier, and straps. All of these features, however, were well-known in the pre-2002 prior art. None is unique to Atrium or Davol's products.

12. Unlike Atrium's V-PatchTM, however, Davol's VentralexTM patch has *no* O3FA coating. The Atrium V-PatchTM's O3FA coating has been shown to minimize visceral tissue attachment to the mesh, and was designed in response to doctors' demands for a better-performing product.

13. Both Atrium's V-PatchTM and Davol's VentralexTM patch come in identical sizes. That similarity, however, is due not to copying but rather to doctors' preferences and the limited range of sizes for the products' shared purpose (the repair of small hernia-related defects).

Availability for Cross-Examination

14. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

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