

Medtronic Unit Hit With \$106.5M Heart Valve Patent Trial Loss

By **Gina Kim**

Law360 (February 8, 2023, 7:14 PM EST) -- A California federal jury on Wednesday ordered Medtronic's CoreValve unit to pay nearly \$106.5 million to plaintiff Colibri Heart Valve in an infringement dispute involving a medical device used for replacing heart valves that is less invasive than open-heart surgery, finding that Medtronic actively induced infringement of the claims in Colibri's patent.

The jury said in its verdict form that Medtronic CoreValve LLC induced infringement of Colibri Heart Valve LLC's inventions and failed to prove that the claims in the patent, U.S. Patent No. 8,900,294, called "Method of Controlled Release of a Percutaneous Replacement Heart Valve," were invalid. The jury awarded Colibri \$106,486,000 in damages.

The invention relates to replacement heart valves that are delivered percutaneously through a patient's skin and via a patient's blood vessel, such as a femoral artery. The percutaneous heart valve delivery method is an alternative to traditional open-heart surgery and is far less invasive and less expensive.

The jury reached its decision after a week of testimony and four hours of deliberations.

Wednesday's verdict stems from a patent infringement action launched in the Central District of California nearly three years ago by Colibri, a Colorado-based medical device company focusing on the research and development of innovative heart valve technologies.

Colibri accused Medtronic CoreValve, a medical device manufacturer, of infringing its groundbreaking artificial heart valve invention and the methods for using the devices. The company further alleged that Medtronic was inducing direct infringement of its '294 patent by third parties, or doctors, who use three types of Medtronic CoreValve devices.

The '294 patent was issued by the U.S. Patent and Trademark Office in December 2014 and expired on Jan. 4, 2022.

Colibri asserted that Medtronic CoreValve, which also manufactures and sells self-expanding heart valves and delivery systems, along with a transcatheter aortic valve replacement, began selling products that infringed its patents. Medtronic CoreValve is a unit of medical device giant Medtronic plc, according to the complaint.

The accused products at issue belonging to Medtronic are the CoreValve Evolut R, which the company began selling in 2015, CoreValve Evolut Pro, which it began selling in 2017, and the CoreValve Evolut

PRO+, which the company started selling in 2019. Medtronic denied that the doctors who use its devices infringed Colibri's patent, and contended that the inventions claimed in the '294 patent were not new or obvious, and therefore invalid.

The inventors behind the '294 patent are Drs. David Paniagua and R. David Fish, interventional cardiologists who founded Colibri in 2010. The doctors worked for years to address the need for treatment options for patients that suffer from crippling heart valve diseases and need new ones, according to the complaint.

According to Colibri's first amended complaint filed in June 2020, the company's inventions include a self-expanding heart valve device that has cross-linked biological tissue and a delivery system that can be guided through an artery to the heart where it is placed and used to replace diseased valves.

Colibri alleged that its patented device and method of controlled release, which includes making a small cut through which a thin, flexible tube is placed into the artery, is much less invasive than open-heart surgery. The controlled release also allows a surgeon to recover the heart valve device during deployment, according to the complaint.

In a statement, a Medtronic spokesperson said the company strongly disagrees with Wednesday's ruling and will continue to vigorously defend against the allegations on appeal.

"As a pioneer in healthcare technology, Medtronic has always been at the forefront of advancing cardiovascular treatment for patients around the world and this decision does not diminish our commitment to our mission of alleviating pain, restoring health and extending life," Medtronic's statement reads.

Counsel for Colibri declined to comment on the verdict Wednesday.

In the spring of 2014, Medtronic agreed to pay \$750 million plus ongoing royalties to Edwards Lifesciences AG to resolve all patent disputes over transcatheter heart valves between the two entities at both the U.S. Patent and Trademark Office and in federal court. The royalty payments were to amount to at least \$40 million annually and to last through April 2022.

The patent-in-suit is U.S. Patent No. 8,900,294.

Colibri Heart Valve LLC is represented by Mieke K. Malmberg of Skiermont Derby LLP, Theodore D. Kwong of Hilgers Graben PLLC, John M. Hughes, Joseph C. Smith Jr., Meg E. Fasulo, Taylor J. Kelson, Steven E. Derringer, Matthew R. Ford and Katherine E. Rhoades of Bartlit Beck LLP and Adam K. Mortara of Mortara Law.

Medtronic CoreValve LLC is represented by Mark D. Fowler, Kathryn Riley Grasso and Martin M. Ellison of DLA Piper LLP.

The case is Colibri Heart Valve LLC v. Medtronic CoreValve LLC, case number 8:20-cv-00847, in the U.S. District Court for the Central District of California.

--Editing by Jay Jackson Jr.

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