Boston Scientific

Boston Scientific Receives Favorable Rulings In Edwards Lifesciences Litigation

Edwards Found to Infringe on Boston Scientific Patents in Germany and U.K.

MARLBOROUGH, Mass., March 9, 2017 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced the German District Court of Düsseldorf has determined that Edwards Lifesciences Corporation and its German subsidiary's Sapien 3™ device infringed two patents of Boston Scientific Scimed, Inc. related to the seals for transcatheter heart valves, specifically the German parts of EP 2 749 254 B1 and EP 2 926 766 B1.

The Lotus™ Valve System is designed for aortic valve replacement in patients with severe aortic stenosis who are considered at high risk for surgical valve replacement. Instead of open heart surgery, the replacement valve is delivered via transcatheter percutaneous delivery. The Lotus Valve Adaptive Seal™ is a technology that creates an external seal to prevent leakage around the valve known as paravalvular leak or PVL, which is a proven predictor of mortality. [i,ii,iii]

Boston Scientific and its German subsidiary were also found not to infringe upon Edwards' German part of EP 1 441 672 B1, but to infringe upon Edwards' German part of EP 2 399 550 B1; however, the company believes that the '550 patent will be revoked by the European Patent Office (EPO).

Edwards Lifesciences and Boston Scientific can appeal each of the four decisions as far as the District Court of Düsseldorf has decided against them. Each company has opposed the other's patents in the EPO.

This decision in Germany follows the March 3, 2017, ruling from the Patents Court of the High Court of Justice in England, which also ruled in favor of Boston Scientific Scimed, Inc., finding that Edwards' Sapien 3 device infringes Boston Scientific patent EP (UK) 2 926 766 and that all claims of that patent were valid. Edwards has stated that it will seek permission to appeal this judgment.

"We will continue to protect our intellectual property to ensure we can continue to bring forward innovative technologies that make a meaningful difference in the lives of patients," said Tim Pratt, executive vice president, chief administrative officer, general counsel and secretary, Boston Scientific. "We are pleased with the progress we are making with litigation in Europe, and believe the strength of our intellectual property will also be upheld in U.S. cases involving the same patents."

The Lotus Valve is currently not available for use or sale.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, clinical trials, regulatory approvals and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[i] Kodali SK et al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement.*N Engl J Med* 2012; 366:1686-1695

[ii] Tamburino C et al. Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis. *Circ.* 2011;123:299.

[iii] Abdel-Wahab M et al. Aortic Regurgitation After Transcatheter Aortic Valve Implantation: Incidence and Early Outcome. Results from the German Transcatheter Aortic Valve Implantation Registry. *Heart* 2011;97:899-906.

SOURCE Boston Scientific Corporation

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