

Boston Scientific Prevails in U.K. Edwards Lifesciences Litigation

U.K. Court Affirms that Edwards Lifesciences Infringes Boston Scientific Patent

Boston Scientific Corporation (NYSE: BSX) today announced the U.K. Court of Appeal dismissed Edwards Lifesciences' appeal and upheld a prior court decision that Edwards' Sapien 3™ device infringes Boston Scientific patent EP (UK) 2 926 766 and that all claims of that patent are valid.

"We are pleased with another positive ruling from the European courts which further substantiates our intellectual property," said Desiree Ralls-Morrison, senior vice president, general counsel and corporate secretary, Boston Scientific. "We see the U.K. court's decision as an important validation of our patents and supports our goal to bring differentiated solutions to patients suffering from severe and symptomatic aortic valve stenosis."

Separately, the company plans to appeal the U.S. Patent Office's recent Inter Partes Review finding that certain claims of the Boston Scientific U.S. patent 8,992,608 asserted against Edwards are invalid.

Boston Scientific currently offers the ACURATE neo™ Aortic Valve System in key European markets. The company is also seeking CE mark application for the next-generation valve system, the ACURATE neo2™, and intends to commercialize the new valve later this year as well as begin a pivotal clinical study for U.S. regulatory filing.

The ACURATE family of valve products is one of two valve systems in the Boston Scientific structural heart portfolio. The LOTUS™ Valve System features an adaptive seal, which 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]

The company continues to have a goal to return the LOTUS Valve to the European market and launch in the U.S. in 2019, pending its ability to clear certain technical and regulatory hurdles.

The ACURATE neo™ Aortic Valve Systems are not available for use or sale in the US. The ACURATE neo2™ Aortic Valve System is not available for use or sale. The LOTUS Valve System 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.eu and connect on [Twitter](#) and [Facebook](#).

References

[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.

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