

## **FTC Sues to Stop Merger of Heart Device Makers**

By Ashley M. Masters, K&B Attorney and Healthcare Practice Member  
[amasters@kingballow.com](mailto:amasters@kingballow.com)

A medical device manufacturer announced on July 31, 2009 it will abandon a merger with a competitor that produces a rival device after the Federal Trade Commission filed a complaint challenging the merger as anticompetitive. Spurred by the interest in controlling national healthcare costs, the FTC is increasing its scrutiny of health care provider transactions.

The FTC claims the proposed merger of Thoratec Corporation and HeartWare International, Inc. would have prevented companies who are currently producing similar products from becoming viable competitors. Thoratec had planned to acquire all voting shares of HeartWare, a company also developing a LVAD, for an estimated \$282 million. LVADs are miniature blood pumps surgically implanted to support and sustain patients suffering from end-stage heart failure.

While mergers between competitors often produce efficiencies beneficial to the companies and to consumers, the FTC may investigate and challenge acquisitions when it believes those efficiencies are outweighed by potential anticompetitive effects. The FTC claims Thoratec holds a monopoly in the US market for LVADs and that the proposed merger would have driven up the price of LVADs, inhibited innovation, and stifled competition from other providers. The July 31, 2009 announcement that the merger will not be pursued was made prior to any public response from Thoratec and HeartWare to the FTC's charges.

Currently, only Thoratec's LVADs, the Heartmate XVE and HeartMate II, have US Food and Drug Administration approval for commercial sale for bridge to transplant therapy. HeartWare is one of a select few companies permitted by the FDA to sell limited amounts of LVADs for clinical trials. HeartWare's device - the HVAD - is allegedly in the latter stages of clinical development and positioned to be the next LVAD approved by the FDA, likely by 2012. The FTC contends other companies developing LVADs are significantly behind HeartWare in clinical trials and unlikely to reach the market as quickly or competitively as HeartWare.

The FTC claims HeartWare's HVAD, upon receiving FDA approval, will present a significant competitive challenge to Thoratec's monopoly. According to the FTC, a Thoratec-HeartWare merger would substantially lessened competition for sales of LVADs by eliminating current and future competition between the two most likely producers. The merged entity would also have been able to maintain its monopoly status and further exercise power over the market.

The ultimate concern with monopoly power, particularly with only one producer in the market, is that the monopolist can unilaterally reduce its output and force higher prices. In this case, the question was whether Thoratec would reduce availability of alternative

LVADs, potentially denying life-saving treatment to patients, and charge higher prices, in the absence of competition by HeartWare.

The FTC also points to potential anticompetitive effects resulting from loss of innovation. In particular, it asserts HeartWare's device offers "a novel design that promises superior reliability with fewer surgical complications." According to the FTC, "[c]ompetition from HeartWare has already forced Thoratec to innovate even though the HVAD is still in clinical trials. The intensity of this rivalry will only increase once HeartWare obtains FDA approval." These assertions were set to be litigated in a hearing scheduled for December 2009.

An FTC official cited health care reform as one reason to ensure competition of medical products. This signals continued and heightened scrutiny of health care mergers and acquisitions and the importance of providers incorporating antitrust considerations into such transactions.

**For more information contact:** Ashley M. Masters, K&B Attorney and Healthcare Practice Member, [amasters@kingballow.com](mailto:amasters@kingballow.com), phone (615) 726-5401.

***These opinions and comments are intended only for the purpose of providing recent updates and general information and are not intended, and should not be used, as a recommendation for any specific situation or entity or as a substitute for legal counsel. Always consult with an attorney for specific legal counsel concerning your particular situation.***