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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
	)	
Thoratec Corporation,	)	
a corporation,	)	
	)	
and	)	Docket No. 9339
	)	
HeartWare International, Inc.,	)	
a corporation.	)	

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Respondents Thoratec Corporation ("Thoratec") and HeartWare International, Inc. ("HeartWare") have entered into an agreement, in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, for the acquisition of HeartWare by Thoratec, which acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

SUMMARY

1. Thoratec's proposed $282 million acquisition of HeartWare threatens to eliminate the one company poised to seriously challenge Thoratec's monopoly of the U.S. left ventricular assist device ("LVAD") market. LVADs are a life-sustaining technology for treating end-stage heart failure patients who have failed other courses of treatment and are likely to die while waiting for a donor heart or are ineligible for a heart transplant.

2. Thoratec's flagship product, the HeartMate II, and its first-generation LVAD, the HeartMate XVE, are the only LVADs approved for commercial sale by the U.S. Food and Drug

Administration ("FDA"). HeartWare is one of a small number of companies developing LVADs, and one of an even smaller number of companies that are permitted by the FDA to sell limited amounts of these devices pursuant to Investigational Device Exemptions. Of these companies, HeartWare alone represents a significant threat to Thoratec's LVAD monopoly.

3. HeartWare's HVAD, which is positioned to be the next LVAD approved by the FDA, offers a novel design that promises superior reliability with fewer surgical complications. [redacted] of Thoratec's competitors, only HeartWare poses a potential significant threat. [redacted] the HVAD will rapidly erode Thoratec's monopoly following the HVAD's projected FDA approval. [redacted] Likewise, [redacted] HVAD will quickly take market share from Thoratec. [redacted]

4. Competition 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 and [redacted] Competition through lower prices and enhanced features will increase the availability and quality of these lifesaving devices.

5. By acquiring HeartWare, Thoratec willfully seeks to maintain its LVAD monopoly, thereby denying patients the potentially life-saving benefits of competition between Thoratec and HeartWare. This conduct is reasonably capable of contributing significantly to Thoratec's maintenance of monopoly power.

6. Thoratec's acquisition of HeartWare will lead to an increase in market concentration that is presumptively unlawful whether the increase in concentration is based on [redacted] market share projections or based on current sales.

7. No other firm has the ability to replace the current and future competition eliminated by the merger. Any merger specific and cognizable efficiencies resulting from the transaction will not offset the transaction's profound anticompetitive effects.

PARTIES AND JURISDICTION

8. Respondent Thoratec is a corporation, existing and doing business under and by virtue of the laws of the State of California, with its office and principal place of business at 6035 Stoneridge Drive, Pleasanton, California 94588.

9. Thoratec is, and at all relevant times has been, engaged in "commerce" as defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is an entity whose business is in or affects "commerce" as defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

10. Respondent HeartWare is a corporation, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 205 Newbury Street, Suite 101, Framingham, Massachusetts 01701.

11. HeartWare is, and at all relevant times has been, engaged in "commerce" as defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is an entity whose business is in or affects "commerce" as defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

THE TRANSACTION

12. On February 12, 2009, Thoratec and HeartWare signed an Agreement and Plan of Merger ("Merger") through which Thoratec proposes to acquire 100% of the voting securities of HeartWare in a cash and stock transaction valued at approximately $282 million.

PRODUCT MARKET

13. There are three product markets in which to assess the effects of the Merger:
    a. LVADs;
    b. LVADs as a bridge to transplant therapy; and
    c. LVADs as a destination therapy.

14. By replacing the function of the left ventricle, LVADs provide full circulatory support for end-stage heart failure patients awaiting a donor heart (bridge to transplant) or function as a permanent therapy for patients ineligible for a heart transplant (destination therapy). LVADs are used only after all other potential treatments, including drugs, surgery, and other medical devices, have been exhausted. For that reason, other products used to treat heart failure are not substitutes for LVADs.

GEOGRAPHIC MARKET

15. The geographic market in which to analyze the effects of the Merger is the United States.

MARKET STRUCTURE

16. Thoratec maintains a monopoly in the U.S. LVAD market. It is the only company with LVADs approved for commercial sale in the United States. The HeartMate II accounts for the vast majority of Thoratec's LVAD sales.

17. HeartWare's LVAD device, the HVAD, is in the latter stages of clinical development and poised to be the first and most significant threat to Thoratec's Heartmate II when the HVAD is approved, as expected, in late 2011 or early 2012.

18. In addition to the HeartWare HVAD, there are several other companies working to develop LVADs. Each of these firms faces significant challenges before their LVADs can be approved. Even if they were to overcome these challenges and gain approval, none of these firms appears to have HeartWare's potential to challenge Thoratec's dominant market position. Moreover, it is unlikely that any other LVADs currently in development will reach the market before the HeartWare HVAD.

19. Under both case law and the government's Merger Guidelines, the Merger is presumptively unlawful. At current sales rates, Thoratec currently accounts for over [redacted] of sales in this market, while HeartWare accounts for [redacted] or more of sales, if measured by all sales, including sales for patients participating in clinical trials.

20. The Merger Guidelines measure concentration using the Herfindahl-Hirschman Index ("HHI"). Under that test, a merger is presumed likely to create or enhance market power (and is presumed illegal) when the post-merger HHI exceeds 1,800 and the merger increases the HHI by more than 100.

21. [redacted] HeartWare's HVAD will take significant market share from Thoratec once the HVAD is approved by the FDA in late 2011 or early 2012. As such, [redacted] the Merger would lead to profound increases in market concentration beginning in 2012. [redacted] HHI increases will range from over [redacted] points in 2012 to over [redacted] points in 2013.

22. Moreover, even with HeartWare's sales currently limited to sales for patients participating in the HVAD's clinical trial, the most recent historical market shares show a post-acquisition HHI of more than [redacted] reflecting an HHI increase of at least [redacted] over pre-acquisition levels.

ANTICOMPETITIVE EFFECTS

23. The proposed acquisition may substantially lessen competition in the relevant markets by, among other things:

a. eliminating current and future competition between Thoratec and HeartWare;
b. maintaining Thoratec's existing monopoly position;
c. increasing the likelihood that Thoratec will exercise market power unilaterally;
d. increasing the likelihood that end-stage heart failure patients will be denied life-sustaining treatments and forced to pay higher prices;
e. eliminating innovation competition; and
f. enhancing the likelihood of collusion or coordinated interaction between Thoratec and other LVAD manufacturers.

ENTRY

24. De novo entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character and scope to prevent or defeat the anticompetitive effects of the proposed acquisition.

25. De novo entry would take more than two years and is difficult, costly, and risky because of the research, development, and regulatory hurdles that companies seeking to market medical devices, such as LVADs, typically face. The FDA classifies LVADs as Class III medical devices, which are subject to its most rigorous medical device approval process.

EFFICIENCIES

26. Extraordinarily great merger-specific efficiencies would be necessary to justify the Merger in light of its potential to harm competition and decrease the availability of these lifesaving devices. Such efficiencies are not present in this transaction.

VIOLATIONS

COUNT I – ILLEGAL ACQUISITION

27. The allegations of paragraphs 1 through 26 above are incorporated by reference as though fully set forth.

28. The Merger would, if consummated, substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II – MONOPOLIZATION

29. The allegations of paragraphs 1 through 28 above are incorporated by reference as though fully set forth.

30. Thoratec has, and at all relevant times has had, monopoly power in the relevant markets.

31. Through the Merger, Respondent Thoratec is willfully attempting to and conspiring to maintain its monopoly in the relevant markets. Eliminating HeartWare, [redacted] a significant competitive threat, is conduct reasonably capable of contributing to Respondent Thoratec's maintenance of monopoly power.

32. Respondent Thoratec's acts and practices are anticompetitive in nature and tendency and constitute an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

COUNT III – ILLEGAL MERGER AGREEMENT

33. The allegations of paragraphs 1 through 32 above are incorporated by reference as though fully set forth.

34. Respondents Thoratec and Heartware, through the merger agreement described in paragraph 12, have engaged in unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that December 28, 2009, at 10:00 a.m., or such earlier date as is determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time, and the Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532, Washington, DC 20580, as the place, when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission and Clayton Acts to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under § 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint, and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge will schedule an initial pre-hearing scheduling conference to be held not later than ten days after the answer is filed by the last answering respondent. The scheduling conference and further proceedings will take place at the Federal Trade Commission,

600 Pennsylvania Avenue, N.W., Room 532, Washington, DC 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (and in any event no later than five days after the answer is filed by the last answering respondent). Rule 3.31(b) obligates counsel for each party, within five days of receiving a respondent's answer, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the acquisition challenged in this complaint violates Section 7 of the Clayton Act, as amended, or Section 5 of the FTC Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Merger is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores competition between distinct, separate, viable, and independent businesses in the relevant markets, with the ability to offer such products and services as Thoratec and HeartWare were offering and planning to offer prior to the transaction.

2. A prohibition against any transaction between Thoratec and HeartWare that combines their businesses in the relevant markets, except as may be approved by the Commission.

3. A requirement that, for a period of time, Thoratec and HeartWare provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in that market.

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to ensure the creation of one or more viable, independent entities to compete against Thoratec-HeartWare in the relevant markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, DC, this twenty-eighth day of July 2009.

By the Commission.

Donald S. Clark
Secretary

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