



ASX ANNOUNCEMENT  
17 JUNE 2005

U.S. DISTRICT COURT MAGISTRATE JUDGE RECOMMENDS  
DISCOVERY IN PATENT INFRINGEMENT DISPUTE

HeartWare Limited (ASX:HTW) advises that U.S. District Court Magistrate Judge Seltzer has made an initial recommendation in relation to the patent infringement action commenced against HeartWare by VentrAssist Pty Limited, a subsidiary of Ventracor Limited (ASX:VCR). In response to these allegations, HeartWare applied to the U.S. District Court to have these legal proceedings dismissed.

Magistrate Judge Seltzer has, for procedural reasons, recommended that Ventracor be permitted to conduct discovery before it can assess whether an application by HeartWare for dismissal of the present legal proceedings can be granted.

HeartWare reiterates that the U.S. District Court has not dealt with the merits of Ventracor's claim. Equally, it has not considered whether HeartWare's subsidiary, HeartWare, Inc., is eligible to take advantage of the safe-harbour exemption in Section 271(e)(1) of the *Patents Act* (USA). Section 271(e)(1) is at the "heart" of proceedings with Ventracor as it specifically provides that the manufacture or use of a patented invention is not an act of infringement to the extent that it is necessary to support an application for U.S. Food and Drug Administration ("FDA") approval.

Importantly, Magistrate Judge Seltzer has recommended that "leave [*be granted to HeartWare to*] renew the motion for summary judgment [*i.e. dismissal*] at the close of discovery". Given the U.S. Supreme Court's recent decision in "the Merck v Integra case", which has broadened the patent infringement immunity under Section 271(e)(1), HeartWare intends to have legal proceedings dismissed once the relevant procedural formalities of discovery are completed.

HeartWare remains confident that it will prevail on its entitlement to rely on the safe harbour exemption for the preclinical activities that it is currently conducting as well as the clinical trials it intends to commence in the near future.

HeartWare Chief Executive Stuart McConchie said "*the Company will continue to pursue the exemption and, given the favourable outcome in the U.S. Supreme Court in the Merck v Integra case, is firmly of the belief that the exemption will ultimately be granted.*"

*HeartWare emphasizes that the U.S. District Court is yet to consider either the merits of Ventracor's claim or the availability of the Section 271(e)(1) safe harbour exemption to HeartWare. HeartWare continues to maintain its view that the present proceedings have no*

*standing and are capricious in nature. We are firmly committed to protecting our patent portfolio and to meeting our stated goals.*

*Whilst it is disappointing that this matter is being litigated, it is our view that judicial review of the facts will confirm that there is no substance to Ventracor's claims. Further, the present proceedings completely neglect the strength of HeartWare's global patent portfolio. "*

Mr McConchie confirmed that the defence of Ventracor's action has not materially impacted HeartWare's cash position nor its ability to execute the plans laid out in its prospectus.

"We remain firmly on track to commence human trials in the first quarter of 2006," Mr McConchie said.

HeartWare has a total of 25 patents: 14 in the United States, 8 in Australia, 1 in Europe and 2 other international patents.

## **About HeartWare**

HeartWare Limited is developing a family of proprietary circulatory heart assist devices, or 'heart pumps', to treat patients with congestive heart failure. Heart failure affects 10 million people globally, with over one million new patients diagnosed every year.

HeartWare's first left ventricular assist device, the HVAD, is expected to commence human clinical trials early in 2006, with first sales planned for 2007. With a volume of 45cc, HeartWare's HVAD is believed to be approximately one third the size of other wearless full output pumps under development.

Further information on HeartWare is available at [www.heartware.com.au](http://www.heartware.com.au)

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