



ASX Announcement (260)  
10 July 2007

## **VIRAX ANNOUNCES ALLOWANCE OF KEY VIR201 PATENT IN THE UNITED STATES**

### **Highlights:**

- **Notice of Allowance received for key VIR201 patent in the USA**
- **Reinforces existing protection provided by existing Co-X-Gene™ technology patents**
- **Extends protection to 2019 in the US market**
- **VIR201 is being developed by Virax as a therapy for HIV/AIDS**
- **HIV/AIDS anti-retroviral therapy market is estimated to be US\$10.6 billion by 2015**

**Melbourne, Australia, 10 July 2007** – Virax Holdings Limited (ASX: VHL) announces that it has secured important additional patent protection for its HIV/AIDS product VIR201.

The Company has received “Notice of Allowance” from the US Patent and Trademarks Office for its Patent Application Number 09/831,307, “Avipox Vector Coding an HIV Antigen and a Cytokine”.

The patent grants a period of exclusivity for VIR201 until 2019 in the USA and provides the opportunity for a substantial increase in revenue. The USA is the major market for HIV/AIDS treatments. Worldwide sales of HIV/AIDS therapeutics were US\$7.1 billion in 2005 and are expected to reach US\$10.6 billion by 2015 (Datamonitor Report, April 2007).

Virax is developing VIR201 as a therapeutic vaccine for the treatment of HIV/AIDS. The therapeutic vaccine approach of stimulating the immune system is in contrast with the existing anti-retroviral treatments that directly target the infecting HIV virus.

VIR201 is already protected by the Virax Co-X-Gene™ technology patents in all major markets including the USA. The allowance of this “composition of matter” Patent Application not only provides additional patent protection for VIR201 but more importantly, significantly extends the period of protection for VIR201.

An analogous patent has been accepted by the European Patent Office. When granted this patent will provide a similar expansion of protection for VIR201 in the important European markets.

VIR201 is a biological drug and intellectual property (IP) and “know how” used in its manufacture is owned by Virax. This “process IP” provides yet further protection against potential competition when product patents expire.

This “process IP” may be the only protection available in many countries of the developing world because patents are unobtainable or not adequately enforced. Clearly this is an important protection to have available in view of the distribution of the HIV/AIDS epidemic in the developing world.

### **Background – Product Protection and Intellectual Property**

A valid patent provides legal protection to the owners or licencees of the intellectual property for the life of the patent. It affords the company a period of exclusivity during which it can seek to recover the considerable investment required to discover and develop a new product.

Virax products are already protected by the patented Co-X-Gene™ technology licensed from ANU and CSIRO. The Company sometimes refers to these as its “umbrella” patents because of their broad scope.

A further barrier of protection can be provided if a patent describing the precise composition of the drug or medicine can be secured. The protection afforded by these so-called “composition of matter” patents is often narrower but can extend the duration of any pre-existing protection as well as reinforce it.

Drugs that are biological in nature (rather than chemical or “small molecule”) can use additional levels of protection. The specifics of the manufacturing and purification processes for a biological drug are often unique and are an inseparable part of the final product particularly from a regulatory and safety viewpoint. These process details (“process IP”) may be protected by patents or remain trade secrets (or both in some instances) and can provide the biological drug with additional protection against potential competition even after product patents expire.

This “process IP” may be the only protection available in many countries of the developing world where patents are unobtainable or not adequately enforced. The concentration of the HIV/AIDS epidemic in the developing world means this is an important protection to have available

## **About Virax**

Virax, based in Melbourne, Australia, is a biopharmaceutical company engaged in the discovery and development of novel immunotherapeutic products for the treatment of cancer, and chronic infectious diseases. The Company’s lead product, VIR201, an HIV/AIDS immunotherapeutic (therapeutic vaccine), recently cleared by the U.S. FDA to begin Phase II trials, has completed two successful clinical trials in Australia with additional, international studies planned. The Company has also submitted an application to the South African regulatory authority (MCC) to conduct a Phase I/IIa trial of VIR201. Funding for the trial has been contributed by a consortium of global and South African resource companies led by BHP Billiton.

Virax’s second product in development, VIR501, is an immunotherapeutic for the treatment of late stage hormone refractory prostate cancer. The Company commenced GMP production and is intending to commence Phase I/II trials in Australia in mid 2008 subject to available funding. The Company has licensed its Co-X-Gene™ technology to Transgene S.A. of Strasbourg, France for use in the USA and Canada for its immunotherapeutic products-TG4001 and TG 4010.

Virax is currently working with its International Biosciences Investment Bank financial and strategic advisers in assessing its options including potential partnering arrangements, financing options and the AIM capital raising process.

Additional information about Virax is available at [www.virax.com.au](http://www.virax.com.au)

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