

## Benitec Patent and Litigation Update

**6 February 2007, Melbourne, Australia:** The Directors of Benitec Limited (ASX:BLT) provide the following update on the status of the patent reexamination and litigation.

### Reexamination

Nucleonics initiated a third party Reexamination at the U.S. Patent and Trademark Office ("USPTO") on 4 October 2004, providing the USPTO with art it asserted invalidated U.S. Patent No. 6,573,099 ("099 Patent"). The USPTO rejected the claims based on the provided art. Benitec successfully overcame the references, and the USPTO withdrew all rejections but instituted new rejections on additional art it had uncovered. Benitec then filed a response, which it believed overcame the rejections of Record.

Nucleonics then requested a second Reexamination, adding art it asserted invalidated the '099 Patent. The USPTO merged the two Reexaminations and recently sent out an Office Action. The USPTO withdrew most of the earlier rejections it made, modified other rejections, and added rejections based on the art Nucleonics provided in its second Reexamination request.

Benitec has reviewed this new material and believes it does not raise any issues that would preclude patentability of the invention disclosed in the '099 Patent. Benitec also believes it has strong arguments for overcoming the art of record. Benitec plans to respond to the rejections found in the merged Reexaminations on or before the Response due date of 24 March 2007.

### Litigation

On 29 September 2005, the Delaware District Court granted Benitec's motion to dismiss the *Benitec v. Nucleonics* litigation based on the Supreme Court's *Merck v. Integra* decision. Nucleonics appealed the District Court decision to the Court of Appeals for the Federal Circuit. The appeal will decide whether the District Court has jurisdiction to permit the *Benitec v. Nucleonics* litigation to continue to be prosecuted in view of the *Merck v. Integra* decision holding that the safe harbor provision of 35 U.S.C. §271(e) broadly protects research and development work activities used to support activities submitted to the FDA. After briefing, on 6 December 2006, the Federal Circuit heard oral argument on the appeal.

On 7 January 2007, the Supreme Court issued a decision in *MedImmune v. Genentech*, which addressed the question of whether a license holder could file suit against a licensor without breaching the license first. The Federal Circuit has requested Nucleonics and Benitec to provide supplemental briefing on what effect, if any, the Supreme Court's decision in the *MedImmune* case has on Nucleonics' Appeal. Benitec is presently awaiting the Nucleonics' briefing on the matter. At present, Benitec believes the recent Supreme Court case does not affect the District Court's determination that the case should be dismissed and Benitec intends to respond accordingly.

## **European Patent**

Benitec filed a European patent application (published as EP1071762) based on the 1998 provisional patent applications. In the examination process in 2005, the European Patent Office (EPO) refused the application over prior art (June 2005) and an alleged insufficiency of disclosure in the application. Benitec and CSIRO have appealed the refusal (Nov 2005), and an Oral Proceedings is scheduled for 24 April 2007 to hear the appeal. In the meantime, Nucleonics Inc have submitted material to the EPO in the form of Third Party Observations, containing several prior art references which they allege are relevant to the patent application. Benitec and CSIRO believe they have good grounds to overcome this material and to be successful in the appeal. Two further patent applications have been filed in Europe and will be prosecuted by CSIRO with input from Benitec, for which Benitec are exclusive licensees in the human field.

“Along with our partners CSIRO and our patent attorneys, we believe we have strong arguments to overcome these objections and will be vigorously defending the claims of these patents” said Sue MacLeman, CEO, Benitec Limited.

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## **About Benitec**

Benitec is an Australian biotechnology company focused on licensing its extensive intellectual property portfolio and developing therapeutics to treat serious diseases using its proprietary ddRNAi technology. Its current therapeutic program is focused on Human Immunodeficiency Virus (HIV). Benitec's RNA-based HIV therapeutic, co-developed with the Center for Biomedicine & Genetics at the City of Hope in Los Angeles, California, will enter Phase I clinical trials in early 2007. For additional information, please visit [www.benitec.com](http://www.benitec.com).

## **Forward-looking Statements**

*This press release contains forward-looking statements that reflect the Company's current expectations regarding future events. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategy, the applicability of the discoveries made therein, the successful and timely completion of clinical studies and the uncertainties related to the regulatory process.*