

Benitec wins crucial court judgement in US Federal Court of Appeals

Second US court supports Benitec gene-silencing intellectual property

23 July 2007, Melbourne, Australia: Benitec Limited (ASX:BLT) has been advised that the US Federal Circuit has issued its decision in the *Benitec v. Nucleonics* appeal, affirming the initial US District Court decision to dismiss the Nucleonics' challenge for lack of subject matter jurisdiction.

"We are delighted with the ruling in this case" said Benitec Ltd CEO, Sue MacLeman.

"This litigation has been ongoing since 2004 and we are pleased that with this second confirmation from a US court we can now fully focus our attention, efforts, and resources toward rebuilding Benitec and developing RNAi therapeutics", she added.

Benitec had originally sought dismissal after the Supreme Court's *Integra v. Merck* decision rendered further litigation on the issues in the case nugatory. Nucleonics opposed the dismissal, arguing that a case and controversy remained.

Nucleonics lost at the District Court and appealed the decision to the Court of Appeals for the Federal Circuit. After the Supreme Court expanded Declaratory Judgment jurisdiction in *MedImmune v. Genentech*, the Federal Circuit requested supplemental briefing to determine if the expanded jurisdiction conferred the necessary case and controversy requirements to continue the *Benitec v. Nucleonics* litigation. The Federal Circuit, in a 2-1 decision, ultimately determined the position advanced by Benitec and its US based attorney's for Nucleonics was correct, affirming the District Court's decision.

The Chairman of Benitec Ltd, Peter Francis said that "Benitec will continue to defend itself against attacks on its patent position and any attempt to narrow the proper scope of Benitec's claims. We are committed to enforcing our leading position over ddRNAi and to ensuring that our shareholders will receive appropriate benefit for the investment they have made over a number of years in bringing this revolutionary technology to market".

Benitec's patented technology, known as DNA directed RNA interference (ddRNAi), employs DNA constructs to induce RNA interference (RNAi) in cells. RNAi is a natural cellular mechanism that selectively knocks down or silences a targeted gene by destroying messenger RNA (mRNA). It is triggered by double stranded RNA, where one strand is identical to the target mRNA. Benitec's DNA directed RNAi

(ddRNAi) technology involves inserting a DNA construct into a cell to trigger production of double stranded RNA, resulting in the destruction of the target mRNA and selectively silencing or knocking down the expression of the target gene.

The ddRNAi approach has several potential advantages when compared with alternative gene silencing technologies under development, such as antisense RNA, and synthetic and chemically modified siRNA. These advantages include more versatile delivery options, simultaneous multiple gene disabling, the ability to silence genes in whole organisms (transgenic ddRNAi), and the ability to control the expression and timing of gene silencing.

Chronology of key events:

March 2004

Benitec Ltd announced that it initiated patent infringement lawsuits in the United States District Court for the District of Delaware against Nucleonics, Inc. to protect its gene silencing technologies. The lawsuit alleged Nucleonics, along with others that have since settled, were infringing issued US Patent No. 6,573,099, entitled "Genetic Constructs for Delaying or Repressing the Expression of a Target Gene."

October 2004

Nucleonics filed a request with the US Patent and Trademarks Office to re-examine Benitec's patents. This process is ongoing.

February 2005

Nucleonics issued invalidity and unenforceability counterclaims against Benitec's patents.

September 2005

The US District Court dismissed Nucleonics' counterclaims.

October 2005

The lawsuit between Benitec and Nucleonics, Inc. previously pending in the United States District Court for the District of Delaware was dismissed without prejudice to future rights.

This resulted because once Benitec determined that the Supreme Court's ruling re *Integra v. Merck* brought Nucleonics' drug development activities within the safe harbor exemption, it filed the motion to voluntarily dismiss on the grounds that no case or controversy existed. As stated in the Memorandum Opinion at the time, "the Court concluded that Nucleonics has not demonstrated that it has produced or prepared to produce a product that would be the target of an infringement lawsuit by Benitec" and therefore "no actual controversy" exists, making dismissal of the case the most prudent course of action.

Nucleonics appealed the District Court decision to the Court of Appeals for the Federal Circuit.

December 2006

The Federal Circuit heard oral argument on the appeal.

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 had 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.

This was provided to the Courts in Q1 2007.

July 2006

Court of Appeals for the Federal Circuit rejects Nucleonics' appeal.

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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). For additional information, please visit www.benitec.com.