EXECUTIVE OFFICE OF THE PRESIDENT THE UNITED STATES TRADE REPRESENTATIVE WASHINGTON, D.C. 20508

NOV 1 7 2004

The Honorable Mark Vaile MP Minister for Trade Deputy Leader of The Nationals Parliament House Canberra ACT 2600

Dear Minister Vaile:

I am pleased to acknowledge receipt of your letter of this date regarding implementation and entry into force of the United States-Australia Free Trade Agreement ("Agreement"). My government shares your view that this Agreement will deepen our economic and business partnership, and offers substantial benefits to both countries. We also share a desire to achieve its full implementation and swift entry into force.

In your letter, you provide information regarding Australia's implementation of its obligations under the Agreement, including commitments to introduce further legislation by the end of 2004 that seeks to address various issues recently discussed by our two governments, and information on how Australia's measures implementing the Agreement will operate. I would like to take this opportunity to provide you our views and comments on these issues.

1. Criminal Offense Provisions

The United States welcomes Australia's commitment to introduce legislation shortly that will amend Australia's law to make it clear that, in order to prove certain criminal offenses, an infringer must be shown to have acted "by way of trade" <u>or</u> (rather than "and", as stated in Australia's current legislation) "with the intention of obtaining a commercial advantage." We are proceeding based on the Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously.

2. Temporary/Incidental Reproductions

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The United States welcomes Australia's commitment to introduce legislation that clarifies the scope of the exception to copyright infringement for temporary copies. We are proceeding based on the Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously.

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3. Copyright Term Transitional Provisions

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The United States welcomes Australia's commitment to introduce legislation to limit the transitional period within which the copyright term extension transitional scheme will apply, as well as Australia's commitment to limit compensation payable under this scheme to restitution for costs incurred. We are proceeding based on the Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously. We remain concerned, however, that the transitional scheme that Australia has adopted, even as it may be amended, is unwarranted and burdensome to right holders, and we intend to monitor its implementation and effect on U.S. right holders.

4. ISP Liability Provisions – Knowledge Requirement and Expeditious Takedown

We welcome Australia's commitment to introduce legislation concerning ISP liability and welcome the additional clarifications provided in your letter regarding the effect of these changes. We encourage you to provide a meaningful opportunity for interested U.S. and Australian stakeholders to comment on other aspects of the ISP regulations. We are proceeding based on the Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously, and to enact the regulations expeditiously.

5. End-User Piracy

We welcome Australia's commitment to introduce legislation clarifying that criminal penalties apply to all acts of infringement on a "commercial scale," as that term is elaborated in our Agreement, including any business end-user piracy activity. We are proceeding based on the Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously.

We also welcome the clarifications provided regarding the scope and effect of criminal remedies for commercial-scale piracy, including business end-user software piracy, under Australia's law.

6. Pharmaceutical Patents

Article 17.10(4) of the Agreement requires Australia to "provide measures in its marketing approval process to prevent" generic producers from marketing a product, or a product for an approved use, where the product or use is covered by a patent. It also requires Australia to "provide for the patent owner to be notified" of any request for marketing approval of a product or use during the term of the patent.

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You have explained how the new notification required by Australian law fits into Australia's arrangements for the Therapeutic Goods Administration and Pharmaceuticals Benefits Scheme listing processes already in place. You have further provided assurances that, through the operation of these arrangements now and in the future, the advance notification required by section 26B(1)(b) of the Therapeutic Goods Act will be given prior to entry into the marketplace to allow patent holders sufficient opportunities to apply to a court for injunctive relief to prevent the entry into the marketplace of potentially infringing products.

If Australia's law is not sufficient to prevent the marketing of a product, or a product for an approved use, where the product or use is covered by a patent, Australia will have acted inconsistently with the Agreement. We will be monitoring this matter closely, and reserve all rights and remedies as discussed below.

We also remain concerned about recent amendments to sections 26B(1)(a), 26C, and 26D of the Therapeutic Goods Act of 1989. Under these amendments, pharmaceutical patent owners risk incurring significant penalties when they seek to enforce their patent rights. These provisions impose a potentially significant, unjustifiable, and discriminatory burden on the enjoyment of patent rights, specifically on owners of pharmaceutical patents. I urge the Australian Government to review this matter, particularly in light of Australia's international legal obligations. The United States reserves its rights to challenge the consistency of these amendments with such obligations.

7. Encoded Satellite Signals

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The United States remains concerned that Australia does not appear to apply criminal penalties to all willful and unauthorized reception and use of satellite signals, commercial or otherwise, as required by our Agreement. The United States is firmly of the view that Article 17.7.1(b) of the Agreement requires criminalization of this activity, including viewing of pirated signals in the home. You have explained that Australia takes a different view with respect to home viewing.

We take note of and welcome Australia's commitment to undertake a prompt review of this situation. We expect that this review will include a full opportunity for participation by U.S. and other interested parties.

We also welcome Australia's commitment to introduce legislation that seeks to criminalize all willful commercial receipt and use of satellite signals that are decoded without authorization. We are proceeding based on the

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Australian Government's commitment to introduce this legislation and have it enacted into law expeditiously.

Our governments have the common objective of fully and faithfully implementing our respective commitments under the Agreement, recognizing that reasonable differences may exist over the interpretation of those commitments. Thus, bringing the Agreement into effect is without prejudice to any future action the U.S. Government may take regarding compliance of Australia's laws and other measures with the Agreement, including existing and proposed laws and measures referenced in your letter and this response.

If subsequent practice reveals problems with the full exercise of U.S. rights I have discussed above, Australia should expect that we will take appropriate remedial action.

I look forward to entry into force of the Agreement on January 1, 2005, and working with you to bring the benefits of this historic Agreement to the people of Australia and the United States.

Sincerely,

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Robert B. Zoellick

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