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PARKES ACT 2600

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Dear Mr McNamara

### **Details-stage Regulation Impact Statement – for assessment**

I am writing in relation to the attached final details-stage Regulation Impact Statement (RIS) prepared by IP Australia for the proposal to implement the Protocol amending the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS Protocol) in Australia.

I am satisfied that the final details-stage RIS addresses the concerns raised in your letter of 3 December 2013, addressed to Ms Fatima Beattie, Acting Director General of IP Australia. The RIS has been revised to fully document the details of consultation undertaken by IP Australia in developing the proposed approach to implementing the TRIPS Protocol in Australia. In particular, further details on the views of stakeholders, including patent holders have been documented, as well as how these views have been taken into consideration, specifically in relation to:

- waiving the requirement for the applicant to attempt to negotiate a voluntary licence with the patent holder in circumstances that are considered urgent by the Federal Court;
- allowing countries that are not members of the World Trade Organization to be eligible to use the proposed system;
- allowing the Federal Court to determine adequate remuneration to be paid by the licensee to the patent holder;
- measures to reduce the risk of diversion of the products from the intended participants; and
- the need for the regime to be as simple as possible. Information on how Australia's proposed approach differs to the Canadian regime is provided.

I consider that the further details included in the RIS demonstrate that the Government's best practice principles for consultation have been observed. Accordingly, I am satisfied that the final details-stage RIS now meets the Government's best practice regulation requirements.

As noted in previous correspondence to the Office of Best Practice Regulation, IP Australia has prepared a single-stage RIS, and as no decision has been publicly announced since the commencement of the new Regulatory Impact Analysis process on 8 July 2013, an options-stage RIS was not required.

I submit the RIS to the Office of Best Practice Regulation for formal assessment.

Yours sincerely

Victor Portelli  
Acting Deputy Director General  
IP Australia  
4 December 2013