



22nd February, 2012

Joint Standing Committee
On Treaties
PO Box 6021
Parliament House
CANBERRA ACT 2600
AUSTRALIA
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Dear Sirs,

Hospira submission on the ratification of the Anti-Counterfeiting Trade Agreement

The Department of Foreign Affairs and Trade (“DFAT”) has unequivocally stated that Australia did not join the Anti-Counterfeiting Trade Agreement (“ACTA”) to drive change in Australian laws. DFAT has also publicised that no new legislative measures are required to implement Australia’s obligations under ACTA. Hospira strongly supports this position and as such, does not oppose the ratification of ACTA.

Hospira’s basis for not opposing ACTA

Hospira notes that while the wording of ACTA allows for the implementation of an over-reaching and onerous system of Intellectual Property enforcement, it does not require it. Hospira agrees with the Australian Government’s position that Australia’s intellectual property regime does not require reform in order to comply with Australia’s obligations under ACTA.

It is clear that certain provisions of ACTA do not apply to patents. For example:

- Chapter 2, Section 3 (Border Measures); and
- Chapter 2, Section 4 (Criminal Enforcement).

Hospira believes in achieving an appropriate balance between the rights of patent owners and the provision of affordable medicines to all Australians, and considers that the exclusion of patents from the operation of these provisions is an appropriate and necessary approach.

Hospira’s recommendations

- 1 ACTA expressly allows parties to exclude Patents and Confidential Information from the remedies provided in Chapter 2, Section 2 (Civil Enforcement). As Hospira supports balanced intellectual property rights in the pharmaceutical sector, Hospira recommends that the Australian Government makes this exclusion.
- 2 The DFAT ‘Factsheet’ published on its webpage refers to ‘counterfeit medicines’. Hospira believes that this reference does not refer to generic medicines, but

rather, to medicines which are un-regulated and therefore, illegal. Hospira recommends that the Australian Government clarifies this statement so that it is clear that it does not include generic medicines.

- 3 The potential implementation of ACTA reinforces the urgency surrounding an unresolved issue currently threatening the generic medicines industry. This issue concerns copyright infringement in the production of Production Information documents which accompany generic medicines. The Australian Government has recently introduced legislation which attempts to ensure that generic manufacturers will not be at risk of copyright infringement when complying with their obligations, imposed by the Therapeutic Goods Administration, to provide product information which is identical to the originator's medicine. However, this legislation is defective in a number of respects. Importantly (amongst other things), this legislation does not deal with potential infringements which occurred before the introduction of this legislation. This issue is currently before the Full Federal Court in Apotex Pty Ltd v Sanofi- Aventis Australia Pty Ltd & Ors NSD 2133 of 2011. Given that the seizure provisions of ACTA apply to goods which infringe copyright, failure to resolve this pre-existing copyright issue may result in the seizure of generic drugs at Australian borders. Accordingly, Hospira recommends that the Australia Government addresses this vital copyright issue in conjunction with its consideration of ACTA.

Yours sincerely

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