

# JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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January 10, 2013

Dear Terry Moore  
Intellectual Property Australia  
Australia

Re: JIPA Comments on the “the text of Pharmaceutical Patents Review –Background and Suggested Issues Paper- on November 2012”

Dear Terry Moore:

The Japan Intellectual Property Association is a non-governmental organization that was established in Japan in 1938, which represents users of intellectual property systems, with about 900 major Japanese companies as members. When appropriate opportunities arise, we offer our opinions on the intellectual property systems of other countries and make recommendations for more effective implementation of the systems. (<http://www.jipa.or.jp/english/index.html>)

Having learned that the “the text of Pharmaceutical Patents Review –Background and Suggested Issues Paper- on November 2012”, on your website, we review your questions carefully and would like to submit our comments as follows. Your consideration on our comments would be greatly appreciated.

JIPA again thanks the Intellectual Property Australia for this opportunity to provide these comments and welcomes any questions on them.

Sincerely yours,

(Hirofumi Ueda)

Chairperson of Medicinal and Biotechnology Committee  
Japan Intellectual Property Association  
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## **8. Submissions**

### **List of questions**

The questions below are those appearing in the text of this paper and may provide ideas for developing your submission. As stated earlier, you should not be limited by these questions if there are other points that you would like to make.

#### **Question 1:**

***Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?***

No, it is not. The patent term extension should be applied to any related patents with any new pharmaceuticals getting in each new regulatory approvals such as a new therapeutic use for active ingredient, a method of manufacture of active ingredient, a new dosage, and a new method of administration for active ingredient.

#### **Question 2:**

***Is the length of the extension of term provided for appropriate?***

Yes, it is. The length of the patent term extension should be applied to any related patents with any new pharmaceuticals.

#### **Question 3:**

***Are the recent amendments to increase the thresholds for the grant of an Australia patent appropriate in the context of pharmaceuticals?***

***If not, why not and what further changes are necessary?***

Yes, they are. It does not subject matter for applicants.

#### **Question 4:**

***Do the systems for opposition and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?***

Yes, the patent systems should be equally provided avenues of challenging for each party.

#### **Question 5:**

***Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?***

Yes, they do. This relief is important procedure to protect import of infringed pharmaceutical product for patentee in this filed.

#### **Question 6:**

***Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?***

Yes, it is.

#### **Question 7:**

***Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?*** Pharmaceutical

Patents

Yes, the current timeframes are appropriate for patents in any fields including pharmaceutical patents.

**Question 8:**

***Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed?***

No, follow-on patents cover inventions for new use of active ingredient, or new formulation of its product. These improved treatments provide any chances to have a significant benefit for patients who need such improved pharmaceuticals.

**Question 9:**

***Is the law on data exclusivity appropriate?***

No, it should be along with European, American (U.S.) and Japanese systems. Regarding 'orphan' drugs and pediatric indication, additional data exclusivity period is necessitated for keeping an incentive of the clinical development.

**Question 10:**

***Are the laws on patent certificates appropriate?***

An original company should be listed at any pharmaceutical patents related with the original product on the ARTG, and 26A to 26D of TGA should be applicable to both of original company and generic company.

**Question 11:**

***Are the laws on copyright of product information appropriate?***

Yes, it is.