AusBiotech submission
regarding IP Australia’s public consultation:
Proposals to streamline IP processes and support small business

To: IP Australia
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Introduction

AusBiotech is pleased to submit to this consultation from IP Australia regarding the proposal to streamline IP processes and support small business, based on input from the Intellectual Property Expert Panel of AusMedtech and from many years of working to grow Australia’s strength in biotechnology.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 500 – 900 medical technology companies) and employs in excess of 45,000 Australians.

AusMedtech, part of AusBiotech, is the national industry group representing the medical devices and diagnostics industry sector in Australia. AusMedtech is dedicated to the development, growth and prosperity of the Australian medical technology industry. The Intellectual Property Expert Panel of AusMedtech is an advisory group made up of experts in IP law and the application of IP in the medical devices and diagnostics (medical technology) industry.

AusMedtech’s objectives are to:
- Provide information to assist better decision-making by medical technology businesses to facilitate success in product development, manufacturing and business;
- Represent the Australian developers and manufactures and focus the industry on commercialisation and export success – taking Australian medical technology to the world;
- Support future sustainability by encouraging links between industry, research bodies and government; and
- Be the leading advocate for industry issues and raise community awareness of the Australian medical technology industry.

AusMedtech’s vision is:
To facilitate the commercial development of an Australian medical device and diagnostics (medical technology) industry.

The Australian Medical Device Industry
The medical technology industry is growing rapidly around the world. The increasing affluence of developed and developing countries, with people living longer and demanding a higher quality of life are all driving this growth.

According to Frost and Sullivan data the global advanced medical technologies market (medical devices, medical imaging and patient monitoring) was worth US$342.8 billion, the Asia Pacific market (including Australia) was worth US$63.5 billion (18.5% of the global market) and Australia’s share was US$6.81 billion (1.98% share). ¹

There are more than 400 medical device companies in Australia. Of these, there are 34 ASX-listed medical device companies (39% of the ASX-listed life sciences market). Total market capitalisation of listed medical devices companies had reached A$12.79 billion by October 2013.²

Medical device companies in Australia, with a few exceptions are typically young and small, competing globally with large multi-national companies for market share. The medical device industry is one of the so-called sunrise industries. It ticks all the boxes on advanced manufacturing, providing high value-added products, with highly skilled labour and global production chains, for specialised markets.

¹ Frost and Sullivan, 2013 Global Medical Devices Outlook
² PricewaterhouseCoopers, 2013 BioForum, Edition 45, Q1, FY14
The industry is also advancing rapidly into new fields of science and engineering, with nanotechnology and other research developments facilitating new innovations in the biomedical sphere and an increasing convergence of physical and biological technology platforms.

**AusMedtech Submission**

*General comment*

AusMedtech is supportive of proposals that encourage Australian innovation and investment. A strong and effective IP system is one of a number of requirements the Australian government must provide to encourage Australian innovation and investment. IP Australia does and must continue to play a leading role in ensuring Australia's IP system balances the needs of all stakeholders. This includes providing high quality and cost effective management of Australia's various IP rights systems.

AusMedtech welcomes the current review and appreciates the opportunity to comment on proposals relevant to the Australian medtech industry. The Intellectual Property Expert Panel of AusMedtech has considered the proposals and provided advice to AusMedtech. Please note that AusMedtech does not have a position with regard to some proposals.

AusMedtech appreciates the opportunity afforded to it to comment on the proposals and would welcome the opportunity to provide further comment at a later stage of the review.

*Specific comment*

1. **Aligning Renewals**
   As a general principle, AusMedtech supports proposals that result in uniformity in approach on key areas across the four IP rights.

   A. **Renewal Grace Periods**
   AusMedtech is supportive of proposals that clarify the position of patents and registered designs as proposed by Option A2.

   B. **Early Payment of Renewal Fees**
   AusMedtech is supportive of the proposal that prevents payment of renewal fees to 12 months before the renewal date (i.e. Option B2).

   It is undesirable that Australian IP rights remain in force in circumstances where the owner of those rights no longer considers the right to hold commercial value. Allowing IP rights to be renewed well in advance can result in owners in effect "paying and forgetting" about their Australian IP rights so leaving in force IP rights that third parties must observe.

2. **Re-examination/Revocation**
   As a net importer of IP, it is important that Australia's IP system provides an effective process for third parties to seek review of the scope of IP rights. AusMedtech supports alignment of re-examination processes across the various IP rights. With regard to patents, AusMedtech agrees that third parties requesting re-examination should have an explicit right to participate in a revocation hearing. However, allowing this must not result in the current benefits of re-examination (i.e. relatively quick, relatively inexpensive third party review) being lost.

3. **Extensions of time**
   AusMedtech is concerned with the proposal to limit extensions of time for "error or omission by applicant/owner" to just 12 months. While very long extensions of time are undesirable, it is occasionally the case that errors are not discovered until 12 months after a relevant deadline. This is particularly the
case where an applicant/owner or their agent has determined the deadline to be one year later than it actually is. It is proposed that 24 months may be a more appropriate timeframe and one that balances the needs of applicants/owners and third parties.

4. Writing Requirements
AusMedtech is supportive of Option 2 that would remove the need for the Commissioner to "decide in writing" whether an innovation patent meets the criteria for certification.

5. Deciding How Documents are Filed
AusMedtech is supportive of an approach that provides a simple, streamlined and uniform approach to the filing of all documentation with IP Australia.

6. Official Journals and Registers
AusMedtech does not see the need for the continuing publication of Official Journals. However, all actions taken by IP Australia for which notification is required must be readily accessible to applicants, owners and third parties.

7. Self-service Amendments
Proposals that facilitate ready correction of obvious errors and changes to owner details are supported. AusMedtech is, however, concerned that any proposals in this area do not jeopardise the current relatively high quality of information held on IP Australia’s records. Third parties must always be able to trust the information held by IP Australia about the holders of IP rights. It is considered important that amendments to details only be allowed by the "address for service" so ensuring that updates are sanctioned by the relevant owner.

8. Signatures
AusMedtech supports removal of the requirement for signatures for the actions listed in the paper.

9. Certificates
AusMedtech is supportive of Option 2 and has no objection to the proposal that certificates be available electronically so long as hard copies are available on request and at no charge to the owner.

10. Address for Correspondence
AusMedtech supports retention of an Address for Service and alignment of this approach across all IP rights.

11. Third Party request for Examination
AusMedtech is supportive of Option 2 that would see third parties provided with an opportunity to directly request the Commissioner to examine a standard patent application.

12. Colour Drawings
AusMedtech supports Option 2 that would allow filing of colour drawings with no extra fee.

16. Multiples copies of representations
AusMedtech supports removal of the requirement to file extra copies of representations (i.e. Option 2).

20. Customs Notice of Seizure
AusMedtech is supportive of Option 2 that would result in Customs having the option to issue relevant notices electronically or through other approved means.