

From: [Michael Caine](#)
To: [TPP IP Policy](#)
Cc: ["IPTA Australia"](#); ["Jeremy Dobbin"](#); ["David Tadgell"](#)
Subject: RE: Invitation to a workshop to discuss proposals to implement the intellectual property changes required to ratify TPP [UNCLASSIFIED]
Date: Tuesday, 22 March 2016 12:22:49 p.m.
Attachments: [image001.jpg](#)

Dear Minister

Thank you very much for the invitation to attend this important workshop. While we would like to have been able to attend and contribute to the discussions, unfortunately due to the timing of the meeting, we do not have a representative available to attend.

While we propose to file a submission in response to the current proposals there are three matters of such importance that we feel the need to raise them in advance of the Workshop.

- 1) The proposal regarding patent term extensions has completely misunderstood the meaning of "unreasonable curtailment of patent term as a result of the marketing approval process". This curtailment of patent term is the term lost as a result of the need to satisfy regulatory authorities in relation to the safety and efficacy of the pharmaceutical product. This includes the time following the filing of the patent application during which the patentee carries out the necessary clinical trials to satisfy the regulatory authorities that the product is indeed safe and efficacious. The time spent by MEDSAFE looking at the regulatory application represents only a part of this delay. Unlike Article 18.46 which clearly refers to "Granting Authority" in the heading and the process of issuing patents, Article 18.48 makes no reference in the heading or otherwise, other than in section (1) requiring efficient processing of applications, to delays caused by the Regulatory Authority. We recommend that the MBIE look at the provisions currently in effect in Australia for providing the compensation referred to in Article 18.48.
- 2) The definition of "biologic" in the consultation paper is erroneous, and shows a complete misunderstanding of the nature of biologic drugs, which are primarily proteins and peptides, including antibodies, produced by recombinant DNA technology.
- 3) In view of the efficient processing of patent applications by IPONZ (as with IP Australia) there is no need to introduce provisions to compensate patentees for lost term as a result of the patent application and examination process. Even though it is unlikely to ever be required, having the provision in the NZ Patents Act will mean that those reviewing NZ patent families, for example following patent searches, will need to check each and every NZ patent found to be certain that no patent term adjustment was applied. This will create significant extra work (and costs) in relation to the carrying out of patent status checks and freedom to operate (infringement) searches in New Zealand for zero net benefit. Australia relies on its efficient processing of patent applications to satisfy this requirement, a requirement which was previously included in the AUSFTA signed several years ago, and we suggest that New Zealand do the same.

We would be grateful if the concerns expressed above could be taken into account in the Workshop tomorrow.

Kind regards

Michael

Michael Caine
Vice President
Convenor, Patents Legislation Committee

IPTA
c/- Davies Collison Cave
1 Nicholson Street
Melbourne VIC 3000 Australia
T: + Redacted s.9(2)(a) OIA 1982
F: +
E:

From: TPP IP Policy [<mailto:tpp.ip.policy@mbie.govt.nz>]
Sent: Thursday, 10 March 2016 3:07 PM
To: TPP IP Policy
Subject: Invitation to a workshop to discuss proposals to implement the intellectual property changes required to ratify TPP [UNCLASSIFIED]

Hello again,

Further to our email informing you of the release of the consultation document on implementation of the TPP IP chapter, MBIE would like to invite you to attend a workshop for key stakeholders in your general area of interest. The purpose of the workshop is to discuss the proposals to implement the intellectual property changes required to ratify TPP.

The workshop will occur on **Wednesday 23 March** from **9am – 10.30am**, at Thorndon 1 Meeting Room, Ground Floor, The Terrace Conference Centre House, 114 The Terrace, Wellington.

Please reply to this email to confirm whether you and/or anyone else from your organisation will attend by COP **Monday 14 March**.

We look forward to seeing you there.

Business Law | Commerce, Consumers and Communications Branch | Building, Resources & Markets |
Ministry of Business, Innovation and Employment
15 Stout Street, Wellington, 6011 | PO Box 3705 Wellington 6140

cid:image001.jpg@01CE732A.1A2F9630



www.govt.nz - your guide to finding and using New Zealand government services

Any opinions expressed in this message are not necessarily those of the Ministry of Business, Innovation and Employment. This message and any files transmitted with it are confidential and solely for the use of the intended recipient. If you are not the intended recipient or the person responsible for delivery to the intended recipient, be advised that you have received this message in error and that any use is strictly prohibited. Please contact the sender and delete the message and any attachment from your computer.

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering.
<http://www.mailguard.com.au/mg>

[Report this message as spam](#)

This email, including any attachments, is only for the intended addressee(s) It is confidential, subject to copyright, and may be the subject of legal or other privilege, none of which is waived or lost by reason of this transmission If the receiver is not an intended addressee, please accept our apologies, notify us by return, delete all copies and perform no other act on the email Unfortunately, we cannot warrant that the email has not been altered or corrupted during transmission Also our network may delay or reject delivery of an email sent to us, so please ensure an acknowledgement of receipt is received if you wish to confirm delivery