

27 September 2013

Sean Applegate
Domestic Policy
IP Australia

Email: consultation@ipaaustralia.gov.au

Dear Sean

RE: Patentable Subject Matter – Consultation on an objects clause and an exclusion from patentability – July 2013

Thank you for asking the Royal College of Pathologists of Australasia (the College) to provide feedback on the above document.

The College would like to make the following comments to the questions raised in consultation paper.

1. Do you have a preference for either of the two options proposed for the Objects Clause?

The College prefers Option 2.

The College has repeatedly stated its concern that the distinction between discovery and invention has not necessarily been articulated or implemented clearly in the activities of IP Australia. The College appreciates that the wording of the Objects Clause is not designed to address this matter. However, this perspective underpins the College's preference for Option 2.

This option refers to the purpose of the patent system being to promote "*innovation and the dissemination of technology*", and then refers to the competing interests of various stakeholders. This places primary emphasis on invention and the technical implementation of the invention ("technology"), and is in keeping with the College's stance.

By contrast, Option 1 refers to the purpose of the legislation "*being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians*" by balancing the competing interests of various stakeholders. One of the stakeholders listed is "*the users of technology*". In the College's view, this reduces innovation and technology to secondary considerations rather than a primary consideration in the acceptance and management of a patent.

Please note that the College is interpreting the terms "innovation" and "technology" as would "an ordinary reasonable and fully informed member of the Australian public", and not as technical legal terms that may be defined on the basis of case law. We submit that

the utility of an Objects Clause would be compromised if its interpretation required the same degree of precise interpretation as the details of the legislation.

2. Do you agree with the wording proposed by ACIP for the patentability exclusion?

The College has reservations regarding the effectiveness of this clause, irrespective of its wording, in achieving the proposed goal. Legislation and regulations already exist that could limit the licensing and utilisation of a patent which poses a threat to the security, safety, or health of the Australian public. There are well-established mechanisms for implementing, reviewing, and amending these provisions.

The proposed wording is very vague referring to “*exclusion for an invention the commercial exploitation [of] which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public*”. This issue is recognised in the ACIP Options Paper on Patentable Subject Matter (page 20). It is unclear on what basis a decision could be made to exclude a legal invention on these grounds.

The College takes no assurance from this option that it would be used to improve the distinction between discovery and invention.

If IP Australia is committed to having the concept of “*ordre public*” included in legislation, then the College has no quarrel with the proposed wording. However, our reservations regarding the utility of this inclusion remain.

3. Do you agree with amending the Patents Act to explicitly provide the Commissioner of Patents with powers to seek advice on ethical matters?

The College is not familiar with the legislative or regulatory constraints that might limit the Commissioner’s ability to seek advice. As a basic principle, we would assume that the Commissioner has the capacity to seek advice as required, and that the taking of this advice should be recognised in the public domain. (Of course, the content of that advice may need to remain privileged).

In previous submissions and discussions relating to other enquiries into gene patents, the College has noted its concern at the lack of consultation by patent examiners when they were initially confronted with patent applications in an unfamiliar field (such as isolated gene sequences). The patent examiners either did not recognise the novel nature of these applications, or chose not to seek advice.

The College is puzzled that the Commissioner would need to “*be given the power to seek non-binding advice, and have the discretion to decide the most appropriate way to do this*”. We agree that the Commissioner should be able to do this, am concerned that he may not already have this capacity, and note that opportunities for appropriate consultation do not appear to have been undertaken in the past. The College is concerned that this new provision will not necessarily be translated into improved decision-making by the Commissioner.

Yours sincerely

Dr Debra Graves
Chief Executive Officer