Australian Government

Department of Health

Submission to IP Australia's consultation on an objects clause and exclusion from patentability

September 2013

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Introduction

The Department of Health (the Department) welcomes the opportunity to make a submission to IP Australia's consultation on proposed amendments to the *Patents Act 1990* to introduce an Objects Clause and an exclusion from patentability.

The key policy objective for the Health portfolio is to ensure affordable access to appropriate and high quality healthcare while supporting and maintaining the biomedical research and innovation activities that are necessary to continue to improve health outcomes. Consistent with these objectives, the Department has contributed to a number of inquiries and reviews into the patenting of isolated human genetic material which have led to the reforms proposed in IP Australia's consultation paper. Notwithstanding the origin of these reforms, we note that they are technology neutral and apply equally to all technologies.

Objects Clause

The Department agrees that the introduction of an Objects Clause setting out the underlying purpose of the patent system and reflecting both its social and economic objectives, would assist in the interpretation of the *Patents Act 1990* where there is ambiguity or uncertainty.

The consultation paper provides two options for the Objects Clause. The first option as recommended by the Advisory Council on Intellectual Property (ACIP) identifies the promotion of Australia's 'national interest' as an objective of the patent system. National interest is a broad concept which we understand may encompass economic, environmental, social, and cultural factors[1], but this does not appear to be well-agreed. The second option developed by IP Australia as an alternative to Option 1, eliminates the term 'national interest' and instead includes a narrow view of how the patent system contributes to the 'well-being' of Australians by 'promoting innovation and the dissemination of technology'.

Both options refer to balancing competing interests of patentees (applicants, owners and rights holders) with those of patent users and 'Australian society as a whole', but do not refer to the need for balance with the interests of Australians as individuals. That is, when weighing the positive effects of the patent system in contributing to the social and economic welfare of society as a whole through the availability of new technologies and developments, the rights and interests of individuals in areas such as access to personal information (including personal health information) should not be neglected.

As an alternative to the options presented in the consultation paper, we suggest that a version should be considered which clearly reflects the wider social and economic welfare objectives of the patent system[2], and recognises the need for balance between the rights of Australians as individuals and Australian society as a whole.

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[1] Council of Australian Governments' Communiqué, *Principles and Procedures for Commonwealth-State Consultation on Treaties*, 14 June 1996

[2] This concept is set forth in the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement to which Australia is a signatory.

Patentability exclusion

The Department supports the introduction of an exclusion from patentability on morality grounds, but considers that the options proposed are too limited.

The options presented in the consultation paper are limited to excluding inventions the 'commercial exploitation' of which would be morally objectionable. We suggest that a broader exclusion should be considered to cover circumstances where the grant of monopoly rights themselves over an 'invention' would be offensive. This could take direction from relevant legislation of countries such as New Zealand and Japan cited below:

> **New Zealand -Patents Act 1953, Section 17[1]**
>
> ***If it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application.***
>
> **Japan – Patent Act 1959, Article 31**
>
> ***[…] any invention that is liable to injure public order, morality or public health shall not be patented.***

We also note that in contrast to the wording of the TRIPS, the option recommended by ACIP replaces 'ordre public or morality' with the contemporary term 'wholly offensive'. The Department considers that this wording is less inclusive than that used within the TRIPS exclusion. The Australian Law Reform Commission notes that 'ordre public' has seemingly broad scope under European patent law[3], and is dependent on the social, economic and moral values of individual member states. Alternative text which has broader scope than the ACIP option, but at the same time employs contemporary language, should be considered. For example, the wordings of the corresponding UK and Japanese exclusions refer respectively to "public policy or morality" and "public order, morality or public health".

The ACIP wording also provides that the hypothetical addressee for the test of 'wholly offensive' should be an "ordinary reasonable and fully informed member of the Australian public". In our view, this presents an unreasonably high bar, as the words 'fully informed' appear to require a member of the Australia public to have more familiarity with the subject matter than the average person.

Implementing the patentability exclusion

IP Australia also seeks views on amending the *Patents Act 1990* to explicitly provide the Commissioner of Patents with power to seek advice on ethical issues, with particular regard to the application of the exclusion from patentability on moral grounds.

The Department notes that ACIP has existing capacity to provide advice on intellectual property matters, and the strategic administration of IP Australia. We suggest the broadening of ACIP's membership to include an ethicist and a community/consumer representative, which would allow it to provide advice on ethical issues and community perspectives to the Commissioner of Patents. We also suggest that it would be beneficial if there was consultation with Ministers of portfolios with relevant social and health responsibilities when candidates are to be considered.

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[3] Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004)