



25 September 2013

Mr Terry Moore
IP Australia
PO Box 200
WODEN ACT 2606

Email: consultation@ipaaustralia.gov.au

Dear Mr Moore

**Re: Proposed Amendments to the Patents Act Regarding Patentable Subject Matter
Consultation on an objects clause and an exclusion from patentability**

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) is the lead standards body for women's health in Australia and New Zealand, and represents almost 2,000 Fellows, as well as trainees and General Practitioner Diplomates.

RANZCOG is dedicated to the establishment of a high standard of practice in obstetrics and gynaecology and women's health. The College trains and accredits doctors throughout Australia and New Zealand in the specialties of obstetrics and gynaecology so that they are capable of providing the highest standards of health care. The College also supports research into women's health and acts as an advocate for women's health care by forging productive relationships with individuals, the community and professional organisations, both locally and internationally.

The Commonwealth Government has responded to three reports on gene patents and patentable subject matter:

- Senate Community Affairs References Committee *Gene Patents Report*
- Advisory Council on Intellectual Property report *Patentable Subject Matter*
- Australian Law Reform Commission report *Genes and Ingenuity: Gene Patenting and Human Health*.

Subsequent to this process, the Government has accepted recommendations to amend the *Patents Act 1990* to introduce:

- an objects clause to provide clarity on the interpretation of the Act, and
- an exclusion from patentability for inventions the commercialisation of which would be considered wholly offensive by the Australian public.

As part of this process, stakeholders have been asked to respond to recommendations as part of the process of finalising amendments to the *Patents Act 1990*.

RANZCOG, in its role as public advocate for women and their families, has a primary responsibility to promote equity of access. Issues concerning patentability of genes are of interest to RANZCOG for a number of reasons, including, for example:

- Genetic testing for heritable diseases, including cancer predisposition, is a fundamental part of the provision of health care to women and their families. The ability to offer risk-reducing surgery to women is among the most effective cancer-prevention strategies currently available in human medicine.
- Genetic testing of pregnancy-associated tissues involves techniques that are progressing rapidly. For example, the ability to isolate cell-free fetal DNA from maternal blood is enabling non-invasive screening for fetal conditions and predispositions.

The patent system is obviously designed to balance the important need to stimulate investment in innovation, which will yield public benefit, with an expectation that the general public (and, in particular, vulnerable members of our society) can benefit from such innovations, but in a way that allows equity of access.

RANZCOG endorses the principle, and the importance, of commercial ventures undertaking research into genetics with a view to providing diagnostic and therapeutic technologies to advance human health and wellbeing. However, it is important that a balance is struck so that commercial advances provide the potential for positive externality (in the economic sense).

With respect to the questions asked in the Discussion Paper:

1. Do you have a preference for either of the two options proposed for the Objects Clause? If so, please explain the reasons for your preference.

RANZCOG supports the second option: 'wholly offensive' to the 'well-informed reasonable person' as this gives reference to members of society who are 'well-enough informed' to understand the important issues at hand, and who are 'reasonable' and not acting through prejudice.

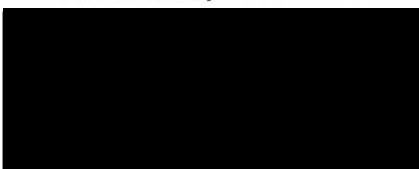
2. Do you agree with the wording proposed by ACIP for the patentability exclusion?

RANZCOG supports the contention that a human cannot be patentable, or genes themselves. This is because the principle of equity of access to diagnostic and therapeutic applications of genes means that these should be available as freely as possible, particularly to vulnerable members of society. However, technical process used as a part of genetic technology should be patentable, to encourage innovation.

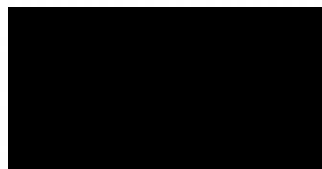
3. Do you agree with amending the *Patents Act* to explicitly provide the Commissioner of Patents with powers to seek advice on ethical matters?

RANZCOG believes it is critical that the Commissioner of Patents be invested with powers to seek advice on ethical matters, from individuals and bodies with sufficient expertise to provide advice.

Yours sincerely



Professor Michael Permezel
President



Associate Professor Steve Robson
Vice-President;
Chair, Women's Health Committee