MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

25 September 2009

The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary,

Re: Question on Notice

Thank you for the opportunity to appear before the Senate Community Affairs Committee on the subject of gene patents on 5 August 2009.

I took the following question from Senator the Hon Judith Adams on notice:

What is Medicines Australia's position on the recommendations of the Australian Law Reform Commission (ALRC) on gene patents [as articulated in the ALRC's 2003 report *Genes and Ingenuity: Gene Patenting and Human Health*]?

Medicines Australia supports a majority of the ALRC's 50 recommendations.

Specifically:

1. We strongly support the ALRC's recommendations:

(i) that patent applications relating to genetic materials and gene derivatives should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology;[1]

(ii) that the *Patents Act 1990* should not be amended to[2]:

---

[1] Medicines Australia favours a liberal test on patentable subject matter. It does not support:
- a "patentable subject matter" assessment for individual inventions, but patentability should continue to be assessed on an individual basis according to existing criteria, which impose sufficient checks and balances; and
- an assessment being done for an entire field of technology.

[2] Medicines Australia believes that the formulation of proscriptive categories of subject matter which are to be excluded from patentability is a crude "on/off" switch, which has the potential to stifle entire fields of innovation. This is particularly so for fields such as pharmaceuticals and other technologies which treat and prevent human diseases, where the risks of failure are high and huge investments of resources are required to understand and then address medical and scientific problems.

In addition, precluding an otherwise patentable invention from grant on the basis that its subject matter is deemed to fall within a proscribed category obviously adversely affects the desire to innovate within that field.

Level 1, 16 Napier Close Deakin ACT 2600
Phone 02 6122 8500 Facsimile 02 6282 6299
www.medicinesaustralia.com.au

- exclude genetic materials and technologies from patentable subject matter;
- exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or
- expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents; and

(iii) that IP Australia should enhance training and develop revised guidelines, consistent with the *Patents Act 1990*, the *Patents Regulations 1991* and existing case law, to assist patent examiners in appropriately applying the patentability criteria to genetic technologies and gene derivatives.

2. In principle, we have no objection to ALRC's recommendations to[3]:

- include "usefulness" as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;
- require the Commissioner of Patents to be satisfied on the balance of probabilities that the criterion of "usefulness" is made out in order to accept an application for a standard patent or to certify an innovation patent; and
- include "lack of usefulness" as a basis upon which an accepted application for standard patent may be opposed, in addition to its current role as a ground for revocation.

3. We support the introduction of a limited statutory experimental use exemption [see Attachment 1]. However, we do not agree with the articulation of certain additional conditions suggested by the ALRC, including:

- the exemption be available only if study or experimentation is the sole or **dominant** purpose of the act;
- **the existence of a commercial purpose or objective does not preclude the application of the exemption**;
- that the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*.

In summary, Medicines Australia, in line with the ALRC, believes that the existing intellectual property system in Australia provides an adequate balance between the competing interests of providing rewards for investment in research and development and the public good. In relation to patent rights specifically, in Australia these provide [a globally accepted] balance between those who are willing to expend tremendous resources to bring new products to market; other skilled persons who utilise "prior art" to improve or transform existing inventions; competitors who wish to enter the market; and society as a whole, which expects and deserves access to innovative products at fair and affordable prices.

New developments in health care are increasingly dependent on significant advances in gene-based technologies. Medicines Australia believes that

[3] However, further discussion concerning the practicality of implementing these recommendations is required. In particular, it is not clear how these would affect the examination process.

uncertainty around the scope of intellectual property rights related to genetic materials and gene derivatives will harm both investment in research and development and, consequently, access to innovative, more effective treatments and diagnostic tests.

Thank you again for the opportunity to contribute to this important inquiry. Medicines Australia looks forward to ongoing dialogue with Government on all aspects of intellectual property rights in Australia.

If you have questions about views expressed in this letter, or if you would like further information, please do not hesitate to contact me at: deborah.monk@medicinesaustralia.com.au or at **02 6122 8500**.

Yours sincerely,

Deborah Monk
Director, Innovation and Industry Policy

Attachment 1

Medicines Australia's Position on Statutory Experimental Use Exemption

In July 2009, IP Australia requested feedback on the following proposed amendment to the *Patents Act 1990*:

A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of...obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.

In its submission, Medicines Australia stated that:

"A general experimental use exemption would significantly expand the exemption applicable under the current regime to pharmaceutical patents only (and for the first time apply that exemption across the board with respect to all other patents, for both methods and products), noting that the regulatory approval identified is very broadly described and applies for the purpose of Australia or any foreign country.

Pursuant to section 119A of the *Patents Act*, the export of pharmaceuticals from Australia for the purposes of obtaining regulatory approval under a law of a foreign country is not permitted unless the term of the patent has been extended under Part 3 of the *Act*. The above proposed amendment does not provide the same limitation and would arguably allow the export of pharmaceuticals for the purposes of obtaining regulatory approval in a foreign country immediately after grant of a patent in Australia. Further, although the exemption may not be intended to extend to commercial purposes, subject to the regulatory framework of the relevant country, commercial quantities of pharmaceuticals could still be exported under of the guise of obtaining regulatory approval in that country. Once exported, the pharmaceuticals could then be re-imported back into Australia (either by the manufacturer or by a third party outside the manufacturer's control) whilst the patent remains valid. The re-importation of such products could (depending upon the terms of the proposed exemption) constitute infringement depending upon issues of notice and exhaustion of rights, however, practical difficulties would arise in terms of identification of product.

Under the *Therapeutic Goods Act 1989*, pharmaceutical companies are entitled to rely upon data exclusivity when applying for registration of therapeutic goods. By way of explanation, "protected information" is information in relation to therapeutic goods that cannot be used by the Secretary of the Department of Health and Ageing in assessing other therapeutic goods for registration. The period of protection of information is not more than 5 years from the date of first inclusion on the ARTG of the product containing the relevant pharmaceutical substance.

The innovative pharmaceutical industry relies heavily upon the above data exclusivity provisions in order to sustain and stimulate innovation. Medicines Australia is concerned that the proposed changes may curtail the existing

data exclusivity rights of innovative pharmaceutical companies, particularly in circumstances where the period of protection of information available in Australia is currently less than the period applicable to Australia's major trading partners. By way of example, the period of data exclusivity in the EU is greater than 5 years.

Any amendment introducing a general experimental use exemption (which may ultimately replace the existing section 119A specific to pharmaceutical patents, as suggested in paragraph 18 of the above consultation paper) could adversely affect the Australian pharmaceutical industry. Section 119A of the Patents Act (as it currently stands) was introduced as an exception specifically for the unique and highly specialised nature of pharmaceutical patents. Similarly, the underlying basis of Part 3 of the Patents Act (under which extension of term of pharmaceutical patents is permitted) is to compensate pharmaceutical patentees for unreasonable curtailment of effective patent life as a result of the marketing approval process.

Whilst some form of limited general statutory exemption applicable to all technologies may be desirable, great care must be taken to ensure that any such exemption is restricted to the activities required for the purpose of any regulatory approval (noting again that the approval concerned is not limited to that required in Australia). The proposed amendment would potentially operate to the detriment of the innovative pharmaceutical industry in Australia.

Therefore, Medicines Australia submits that section 119A of the Patents Act should continue to operate in its current form and the introduction of a general experimental use exemption should be avoided until the ramifications for pharmaceutical patents (and potentially other technologies) are properly considered. Adopting a "one size fits all" type of approach for the sake of consistency may not necessarily meet the interests of all stakeholders."