27 September 2013

Ms Terry Moore
Director, Domestic Policy
IP Australia
PO Box 200
WODEN ACT 2606

Dear Ms Moore

Thank you for the opportunity to comment on IP Australia's latest consultation paper on patentable subject matter.

Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to the Australian market. Last year, our industry generated more than $4 billion in exports and for the third consecutive year, invested over $1 billion in research and development.

Medicines Australia agrees that inserting an Objects Clause in the Patents Act may assist in more clearly defining the purpose of the patent system in Australia: to encourage innovation. We also agree that patent law in Australia must remain technology neutral, and that a new Objects Clause must not be allowed to undermine this fundamental feature of the existing system.

Medicines Australia would support the adoption of the second of the two options proposed for the Objects Clause. Unlike the first option, the second explicitly recognises that the purpose of the patent system is to "promote innovation" and enable "the dissemination of technology".

However, Medicines Australia would strongly caution against the inclusion of words which suggest that the interests of patent holders are inherently (and in all circumstances) incompatible with the interests of society as a whole. The pharmaceutical industry, for example, develops medicines and vaccines which Australians use to lead healthier and more productive lives. In this case, as in many others, the interests of patent holders are exactly the same as those of society as a whole, that is to enable access to the latest and most effective treatments.

Medicines Australia recommends that the word "competing" be deleted from both forms of the proposed Objects Clause. The reference to "competing" interests misrepresents reality and unduly prejudices patent holders. The amended clause(s) would therefore state "…by balancing the interests of…"

Whilst Medicines Australia, in principle, supports amending the general patentability exclusion criteria in line with the Advisory Council on Intellectual Property's (ACIP)

recommendation, the implementation of the recommendation in its current form may have unintended consequences.

The ACIP proposed excluding inventions from patentability "the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public". This recommendation was clearly an attempt to provide a mechanism for dealing with ethical issues in a manner which provides the flexibility to consider inventions on a case by case basis and to accommodate changing community values.

However, adopting the ACIP's recommendation in its current form could create some very serious practical issues. For example, would all patent examiners, for the purpose of law, be considered *a priori* "reasonable and fully informed" members of the Australian public? If so, could individual patent applications be rejected on the basis of the views of individual patent examiners, even though such views may differ from those of his or her colleagues or even society as a whole?

There has been considerable debate in Australia on whether to ban patents on biological materials. Medicines Australia asserts that the matter was resolved in 2012 by the Senate Committee on Legal and Constitutional Affairs. The Committee, in line with views expressed by an overwhelming majority of stakeholders (including Medicines Australia), asked the Australian Parliament to reject a (proposed) law that would have excluded biological materials from patentability.

Despite this, the debate on so-called "gene patents" continues, which means that if the ACIP's recommendation were adopted in its current form, it is conceivable that an application seeking a patent on a biological material may be rejected by a patent examiner who is considered by law to be a "reasonable and fully informed" member of the Australian public, but who nevertheless subscribes to the (minority) view that biological materials should not be patentable.

Unless the ACIP's recommendation were amended to address these concerns, Medicines Australia believes maintaining the current wording relating to patentability exclusion criteria in the Patents Act may be a better option. The current wording is not only consistent with international norms but also has an extensive interpretive history associated with it (which gives IP Australia and Australian courts a clear mandate when it comes to deciding which inventions can or cannot be patented).

Finally, Medicines Australia does not support amending the Patents Act to explicitly provide the Commissioner of Patents with powers to "seek advice on ethical matters" when applying patentability exclusion criteria to individual patent applications. Medicines Australia does not believe it is within the scope of the IP Australia's responsibilities to first seek advice on ethical questions and then determine whether such advice has a material impact on individual patent applications.

Ethical issues represent an especially difficult set of considerations since they reflect personal views which generally change over time. Adopting IP Australia's recommendation would create significant uncertainty for anyone filing patent applications in Australia; not only would they have to satisfy the technical requirements of the Patents Act but they could also be forced to comply with an

individual's views on ethical matters (which may or may not be reflective of the views of the general public).

Medicines Australia contends that the Australian Parliament, and not IP Australia (or its contracted advisors), should have the authority to debate ethical questions in relation to patentable subject matter.

There is a strong and enduring rationale for making sure that no new laws are implemented that would, in any way, undermine the ability of patent owners to acquire or defend their legitimate rights.

The process of bringing new medicines to the market involves a high degree of risk. Only a small portion of promising research yields safe and effective products, of which only a fraction are profitable enough to generate the necessary investment returns. On average, the cost of bringing new medicines to market is approximately $1.5 billion, including the cost of unsuccessful research projects, and it can take between 12 and 15 years to complete the process. Compared with other areas of technology, the time taken to develop new technologies in the pharmaceutical industry is significantly longer.

By guaranteeing a clearly defined period of market exclusivity, patents and other forms of intellectual property rights such as data exclusivity act to mitigate the commercial risks of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in R&D for new medicines. Patents allow companies to invest in R&D, with the expectation that they will have a fair and reasonable opportunity to recoup this investment before others, who did not bear any of the initial risk or costs, are permitted to profit from both new as well as improved products.

A strong, stable and predictable intellectual property system is critical to Australia's ability to attract investment in R&D and high-tech manufacturing. It is also critical to Australian patients being able to receive the latest treatments as quickly as possible.

Medicines Australia looks forward to an ongoing engagement with IP Australia as it continues its consultation on reforms to improve Australia's patent system.

Yours sincerely

Dr Brendan Shaw
Chief Executive