IP AUSTRALIA

PATENTABLE SUBJECT MATTER

SUBMISSION

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

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1. Introduction

The Walter and Eliza Hall Institute of Medical Research (WEHI) welcomes this opportunity to provide input into proposed amendments to the *Patents Act 1990* that relate to a) introducing an Object Clause and b) proposing an exclusion from patentability for inventions that are considered to be offensive.

Being a not-for-profit research institute, WEHI's core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. We are committed to translation of our discoveries, both clinically and commercially. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most of our funds. The majority of our commercial returns are re-invested back into further biomedical research. Further information about WEHI can be found in Appendix 1

Response to specific questions in the IP Australia Consultation Paper (July 2013)

Objects Clause

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

WEHI agrees that an Objects Clause can assist in the interpretation of the *Patents Act* and in guiding interpretation by a court, legislators, examiners, patent applicants/owners and the public. A critical aspect is to ensure that such a clause upholds the principles of technology neutrality as it relates to the Australian and global patent systems.

WEHI prefers IP Australia's Option 2 for the Objects Clause being:

> *"the purpose of the patent system is to provide an environment that enhances the well-being of Australians by promoting innovation and the dissemination of technology and by balancing the competing interests of patent applicants and patent owners, the users of technology, and Australian society as a whole."*

Option 2 considers the interests of both patent applicants and owners. By promoting innovation and dissemination it is reflecting the role of the patent system to provide incentives to innovate and to disseminate knowledge. It also accounts for the interests of patent applicants, owners, Australian society and the users of technology. We further recommend that for completeness and integrity of the Australian patent system, inventors should also be included as follows:

> *" ….balancing the competing interests of inventors, patent applicants and patent owners …"*

Patentability Exclusion

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

In Australia, the *Patents Act* does not include an '*ordre public* and morality" exclusion as allowed but not insisted by Article 27.2 of TRIPS. There is inherent ambiguity in the concepts of "*ordre public*" and "morality", how these are used in national patent law, and understanding that they are

not interchangeable concepts but sometimes confused[1]. The concept of individual "morality" is not differentiated from the obligations of collective "ethics". Our major concern is that the proposed amendment is a relic from unclear historic patent law that adds nothing to clarification and interpretation, particularly for issues that can be addressed through other mechanisms. Importantly, the proposed amendment will blur Australia's ability to distinguish between law, legislature, ethics and morality.

We understand that Section 18 of the *Patents Act* does exclude from patentability human beings and the biological processes for their generation and Section 50 excludes inventions that are contrary to law. We understand and agree with ACIP that Australian patent law must be compliant with TRIPS and cannot exclude an invention because it is prohibited by Australian law.

The ACIP report recommended replacing Section 50 of the *Patent Act* with the following express exclusion from patentability:

> *"….exclusion for an invention the commercial exploitation which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public."*

We note that for various reasons countries such as Japan, New Zealand and India have invoked such an exclusion. Canada, like Australia does not have an "*ordre public* and morality" exclusion and the US does have a morality doctrine which has been rarely used. We do not see any compelling reason for introducing such an exclusion and argue that Australia already has other measures to address issues. Importantly, there has been no compelling argument for the value of such an amendment, particularly given the questions that it will immediately raise.

It would seem that the last decade's debate about gene patents has been the only driver of such a suggestion, with Australian reviews consistently reaching the same conclusion with respect to patentability. Exclusions can hinder research and development in a particular field and in some instances, use of the crown use provisions and compulsory licensing may be a better alternative. It is essential that Australia retain a technology neutral patent system and addresses equity of access and ethical issues through other means.

As a consequence, we disagree with all elements of the wording. In our opinion it would be near impossible to reach concensus with respect to the ACIP wording, implementation and interpretation, and note the following serious questions:

1. What is "*wholly offensive*" as opposed to partly offensive? How would this be determined? What claims of the BRCA1 patent were wholly offensive?
2. Who is an "*ordinary reasonable and fully informed*" member of the public?
3. How many such people would be required for a determination? How will consensus be reached when there is no consistently accepted legal definition of "*ordre public*", "morality" and "ethics"
4. Will an invention only be assessed by an Examiner at examination stage and brought to the attention of the Commissioner?
5. Will the Examiner or Commissioner assess an invention after third party scrutiny? Who would such third parties be?
6. What about granted patents?
7. How will the Examiner or Commissioner determine who is an ordinary, reasonable and fully informed member of the Australian public? The ALRC has already predicted that the courts will determine this over time, so litigation is expected.

[1] See Barbosa DB, Grau-Kuntz K (2010) Exclusions from patentable subject matter and exceptions and limitations to the rights. World Intellectual Property Organisation (SCP/15/3; Annex III)

8. What will happen if not all uses claimed in a patent application are considered wholly offensive?
9. Will there be a "quota" on exclusion applications? What will be threshold for "significance" and offense?
10. Would such an exclusion be best left to our Federal Parliament to regulate because the invention could be exploited and researched with no patent rights?
11. Will there be a review and appeal mechanism? What is the mechanism and at what cost? What will be the compensation for lost returns?
12. What is the actual social and economic benefit of such an amendment and how will it be superior to other mechanisms? Why add uncertainty when it is not required?

Importantly, positions on morality change over time and have strong cultural and spiritual influences. We would only need to consider the evolution of our society with respect to contraception, IVF, stem cells, transfusions, vaccination, gambling machines and abortion to observe major shifts in attitudes to inventions that have been patented. The patent system should not be used for policing transient cultural values and judging morality, and must not be confused with what is considered legal or ethical – we have other comprehensive mechanisms and a legislature and regulation for such determinations.

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

ACIP recommended that the *Patents Act* be amended to provide the Commissioner with power to seek advice on ethical matters. This raises concerns since the proposed exclusion has attempted to cover "public order" and "morality", and now introduces "ethics" without any attempt to define these terms as they relate to Australia.

While we agree that it is important that the Commissioner has the ability to seek advice and consult with third parties with respect to ethical and moral questions, attempts to amend the *Patent Act* must address several difficult questions in the face of no evidence that such a formal amendment is required and will add value.

Major concerns are as follows:

1. How will the examiner decide whether it is a moral and/or ethical issue? They are not the same.
2. What training will examiners have to assess when such questions arise?
3. How would "experts" be selected for the purpose of such advice? How many? What cultural, ethnic, spiritual and educational background? National or international?
4. What happens when the experts are in disagreement? How is a decision made? How is it implemented?
5. Will the patent applicant be provided with a detailed report on the reasoning, outcome, timelines and opportunities for review?
6. Will such an amendment be retrospective and if so for how long?
7. What is the associated cost and compensation?
8. Will excluded patent subject matter be regularly reported to TRIPS signatories?
9. What happens when public opinion changes, by how much, and how would such opinion be measured for each excluded patent?

Therefore, we do not agree that the *Patent Act* be explicitly amended. The Commissioner should have the right to seek advice without changing the Act.

Appendix 1: Overview of WEHI's patenting and licensing activities

Founded in 1915, WEHI is Australia's oldest medical research Institute (MRI) and has a strong track record of research, capture and management of intellectual property and translation of research into medical outcomes. We have extensive experience of the Australian and international patent systems. WEHI currently invests approximately $98 million per year in medical research. Most of these funds are provided by public funding agencies such as NHMRC[2] and NIH[3]. More than 825 full-time equivalent employees and post-graduate students underpin our research efforts. Approximately 80 research laboratories focus on major medical challenges associated with cancer, immunity, autoimmunity, inflammation and infectious disease. We have extensive research collaborations and licenses with private sector partners such as Genentech, Abbvie, Becton Dickinson and Merck in the US, Cancer Research Technologies, GSK, Novo Nordisk and Servier in Europe and CSL, Bionomics and Cancer Therapeutics CRC in Australia.

As a not-for-profit, tax exempt research institute, our core business is the conduct and dissemination of world-class medical research, with the goal of improving human health.

A generally strong organisational understanding and engagement with the global IP system underpin WEHI's activities. Importantly, our initiatives to improve translational outcomes include a) in-house patent prosecution, b) a business development intern scheme for early career scientists, c) routine laboratory notebook audits, and d) a small fund for investment in proof of principle experiments. A portfolio of more than 250 research projects feeds WEHI's discovery and innovation pipeline and in the last 11 years we have:

- Contributed more than 2,800 highly cited publications
- Entered into approximately 2,700 Material Transfer Agreements with academia and industry
- Evaluated 215 significant invention disclosures
- Lodged more than 140 patent family applications
- Entered into more than 620 collaboration and commercial agreements, the majority of which include IP and licensing provisions

WEHI's model for engagement with commercialisation partners is pragmatic and flexible. At any one time several licensing discussions are ongoing and these result in collaborative development agreements with established companies, small and large, as well as the creation of new spin out companies such as Genera Biosystems, Nexpep/ImmusanT, Murigen, BACE Therapeutics and Catalyst Therapeutics.

[2] National Health and Medical Research Council
[3] National Institutes of Health (US)