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Committee Secretary
Senate Standing Committee on Community Affairs
Parliament House
Canberra ACT 2600

Re: Gene Patents Inquiry – Supplementary submission

Dear Mr Humphery,

We would like to thank the Committee for giving IP Australia the opportunity to contribute to this important inquiry.

We appreciate that the Committee has a challenging task before it. Patenting of biological material raises strong and polarised views. It is a sensitive, complex and multifaceted issue in which law, ethics, innovation, research, and healthcare policy intertwine. There are risks in considering any of those aspects in isolation as a change to address one aspect could have unexpected and significant consequences for Australian healthcare, business and trade interests. A holistic perspective is necessary to pave the way for balanced solutions to achieve the goal of affordable access to healthcare and stimulation of biomedical research and innovation. We hope this supplementary submission may further assist the Committee in this regard.

Importance of patents – domestically and internationally

Patent protection is a key government mechanism (amongst others) that supports innovation and translation of basic research into products the community wants. Patents are necessary for the public sector to attract collaborations with the private sector and gene patents in particular to create pioneering medical biotech spin-off companies in Australia. Advancements in cutting edge research and commercialisation are time-consuming and can be very expensive and risky. Patents provide an incentive mechanism for recoupment of these costs by investors. A robust patent system is also essential to ensure that innovative treatments developed overseas are made available in Australia.

Internationally all developed countries and our major trading partners, including the European Union, the US, UK, Japan, Korea and emerging economies of India and China, allow patenting of isolated biological materials, including isolated human gene sequences for which a practical use is identified. This is reflective of a principle underpinning the Australian federal patent system since its inception in 1904 – that patents should be available for all products and processes that have a practical use.

Any deviation from international standards should be based on compelling and strong reasons as to why Australia's circumstances are special. It should also be cognisant of the consequences flowing back to Australia, including whether changes will negatively affect Australia's access to the latest advances in diagnostics and drugs, and our participation in international collaborations. Harmonisation with the global environment is particularly important to a relatively small and geographically isolated country like Australia.[i] The patent system is one mechanism which allows Australians to tap into the 98% of knowledge being developed internationally.

Cost and provision of healthcare – lack of empirical evidence

We wish to highlight the lack of empirical evidence provided to the Inquiry identifying adverse impacts caused by gene patents. In our opinion, there has been no evidence that patents have resulted in any person being *denied access* to molecular genetic testing ('genetic tests'). Instead concerns relate to anecdotal evidence and what hypothetically could happen in future in terms of patentee licensing behaviour, costs and availability of genetic tests.

The Inquiry has heard that while some genetic tests provided to patients are free, the cost borne by the relevant health authority can be substantial. Moreover, the cost is not directly correlated to the patent status or its enforcement. A case in point is the susceptibility to breast cancer test (BRCA) where in evidence the Department of Health has noted its understanding that the price of the BRCA tests proposed by the Australian patent licensee was *'pretty much on par'* to that currently charged by the State laboratories.

On the issue of 'monopolisation' or single provider of tests, we note that over 55% of the 437 genetic tests performed in 2006/07 in Australia were offered by one laboratory.[ii] Our understanding is that the provision of a single provider for these tests is uncorrelated with the existence of patents, for example, many of the tests did not seem to be subject to a patent in Australia. This statistic and a recent public consultation draft report by the US Secretary's Advisory Committee on Genetics, Health, and Society indicates that many market factors other than patents and exclusive licensing arrangements determine whether tests are provided by one laboratory and the prices charged for the tests. These factors include demand and market size.

We acknowledge and support the heartfelt concerns put to the Inquiry for affordable access to healthcare. Patents should stimulate rather than impede research and development in the prevention, management and treatment of human diseases. However, we are concerned about the lack of evidence that gene patents are the root of perceived problems, and particularly the suggestions that an exclusion from patentability of genes or other biological materials will necessarily achieve these outcomes.

IP Australia does not support the broad exclusion proposed by the Cancer Council of Australia to '*biological materials ...which are identical or substantially identical to those that exist in nature*' (under the advice of academic Dr Luigi Palombi). Such a broad exclusion would capture a large proportion of healthcare inventions in the biotechnology and pharmaceutical industries as well as in other industries. Under the proposed exclusion these inventions, although novel, useful and involving an inventive step, would no longer benefit from patent protection. Such exclusion would adversely affect access to affordable future healthcare innovations, the competitiveness of Australia's biotechnology industry and reduce investment in Australian research and development. For example, under the proposed approach inventions such as Gardisil (the cervical cancer vaccine) would not be patentable in Australia but would be in other jurisdictions which could have negative consequences for access and price in the Australian marketplace.

The way forward

If substantial problems arise, existing safeguards in the patent system such as the Crown use and Compulsory licensing provisions can be used to ensure that access to essential services and treatments are not blocked by patents. These are powerful provisions which already exist but it would appear that users of patents may benefit from greater understanding and awareness of these provisions.

In our original submission we pointed the Committee to the Organisation for Economic Co-operation and Development (OECD) guidelines for the licensing of genetic inventions and the Australian Law Reform Commission (ALRC) recommendations to ensure that publicly funded research, where commercialised, results in appropriate public benefit.

We also note with interest suggestions such as patent pools and use of a 'Licences of Right' scheme in submissions to encourage broader and more active licensing of patents.

Patent Pools

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership.

Patent pools have been quite successful in the software and consumer electronics industries, for example, involving inventions whose use is essential to comply with a particular technical standard such as the DVD-ROM and DVD-Video formats. The MPEG-2 patent pool relating to a digital video compression standard has helped to reduce the cost and burden of individual licensing of more than 425 essential patents owned by more than 20 patent holders.[iii]

The establishment of patent pools tends to be driven by industry on a voluntary basis, governments have little role in their creation. However, governments can create incentives and provide the appropriate institutional framework to actively encourage setting up of patent pools in any particular technology field.

Recently, the World Health Organization (WHO) has encouraged creation of patent pools in cases where there is a significant public interest. For example, it is currently developing a patent pool relating to patent rights over gene sequences for the SARS virus. While genetic testing is not currently subject to 'technical' standards similar to those in the software industry, some standardisation is evident with the WHO announcement in 2007 of the first international standard for a human genetic test, Factor V Leiden.[iv]

If more biotechnology based standards become officially endorsed they can become organising principles around which patent pools could be formed.[v] The Committee has been informed of the Australian Therapeutic Goods Administration's plans to introduce a regulatory framework for genetic testing of in-vitro diagnostics (IVD) treating them as Class 3 IVD medical devices. These regulatory standards will apply whether or not the test is reimbursed by Medicare and may also play an important role in incentivising the creation of patent pools.

Should the Committee choose to make a recommendation on this topic, we suggest that it should be contingent on further analysis as there is little experience within Governments to incentivise, facilitate or regulate patent pools.

Licence of right scheme

The UK patent office has had a Licence of Right scheme since at least 1907. Under its scheme, a patent holder may choose to have an entry onto the patent register indicating that licences under its granted patent are available 'as of right'.[vi] The patentee must then grant a licence to anyone wanting one; however, the parties still need to agree on licence terms, or failing agreement the terms are settled by the patent office. In exchange, the patentee gets a 50% reduction in annual renewal fees for patents participating in this scheme.

The idea of the scheme was to encourage uptake of licences and the sharing of patented technology. The uptake is reasonably low, some 8,000 (up to May 2009) and predominantly in electronics and automotive technologies. While the uptake is low the UK patent office advises that it regards the scheme as being of some success and a positive step towards increasing the use of information contained in patents in the market.

IP Reforms

As noted in evidence, Australia's current patent system can and should be improved. IP Australia's proposed patent reforms have their origin in recent jurisprudence and various recommendations made in previous reports by the ALRC and Advisory Council on Intellectual Property (ACIP) and by Dr Terry Cutler in his National Innovation System review. We believe the recommendations of those bodies remain applicable. The package of proposed reforms and initiatives regarding licensing models, forms a solid and measured package of solutions to address concerns the Inquiry has heard.

One of the roles of the patents system is to diffuse knowledge of earlier inventions to encourage more research and creation of follow-on inventions. We have heard concerns that the system is failing to achieve this objective because of some researchers being unsure about their ability to research on and around patents. We agree that it is time to introduce a statutory research exemption to provide clarification and certainty to researchers.

The proposed statutory research exemption should provide patentees, researchers and businesses with greater certainty as to the types of experimental activities that can be done without infringing a patent. The exemption is presently being developed, having regard to the comments received from the recent round of public consultations, our international obligations and the way in which modern research is conducted by institutes and universities.

Other features of the patent reforms will advance the public interest, competition and innovation aspects of Australia's patent system by raising the thresholds set for grant of a patent. The four key elements include:

- Stricter requirements to prove an invention's usefulness at examination and require experimental results showing that the patented invention has utility. These changes to utility will not go so far as requiring applicants to demonstrate their invention's efficacy in humans (as has been suggested by some comments to the Inquiry) as that level of experimental evidence is unrealistic at the early stage of seeking patent protection.

- Raising the inventive step threshold to expand the prior art considered when assessing inventive step and raising examination standards for inventive step.

- Raising the threshold for disclosure requirements to require that patent specifications describe inventions in sufficient detail to enable the invention to be performed across the full scope of the claims. This will limit the reach of claims so that the protection given to an inventor is not disproportionate with what has been described.

- Raising the level of proof with respect to all patentability criteria from the current mix of 'balance of probabilities' and 'benefit of the doubt' to a 'balance of probabilities' evidentiary standard.

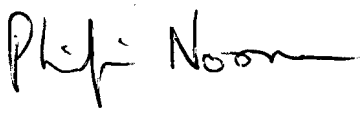
Non-patent levers

The Committee may also wish to take advantage of non-patent policy levers. For example, healthcare and ethical issues respectively have been managed via the Pharmaceutical Benefits Scheme to ensure affordable access to cost-effective drugs, while stem cell research is currently regulated to uphold ethical and community standards in that area.

IP policy changes can sometimes take a back seat to other pressing issues before government. We hope that the Committee will lend its support to these reforms and through its recommendations will provide further momentum to ensure they are given appropriate legislative priority.

Should you require elaboration on any of the above issues, we would be happy to answer any questions. We look forward with interest to the release of your report.

Yours sincerely



Philip Noonan
Director General
IP Australia

30 September 2009

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[i] *Venturous Australia*, Chapter 2 at page 20.

[ii] *Report of the Australian Genetic Testing Survey 2006* prepared for the Royal College of Pathologists of Australasia dated 2 September 2008, page 13. The report is available at http://www.rcpa.edu.au/static/File/Asset%20library/public%20documents/Media%20Releases/AustralianGeneSurvey2006.pdf

[iii] Futa in Overwalle G. V., et al (2007), *Dealing with Patent Fragmentation in ICT and Genetics: Patent Pools and Clearing Houses*, page 3. The article is available at http://outreach.lib.uic.edu/www/issues/issue12_6/vanoverwalle/

[iv] http://www.who.int/mediacentre/news/releases/2004/pr84/en/ visited on 24 September 2009

[v] Takenaka, T. (2009) *Patent Law and Theory: A Handbook of Contemporary Research*, page 719

[vi] *Patents Act 1977* (UK) section 46(1)