



Australian Government

Department of Health

Submission to the Productivity Commission
Inquiry into Intellectual Property Arrangements

November 2015

1 Introduction

The Department of Health (Health) welcomes the opportunity to make a submission to the Productivity Commission's (the Commission) inquiry into Australia's intellectual property (IP) arrangements.

Health has a diverse set of responsibilities to lead and shape Australia's health system and sporting outcomes through evidence based policy, well targeted programmes and best practice regulation.

In discharging its portfolio responsibilities in the healthcare sector, Health regularly encounters issues relating to IP rights (such as patents, trademarks, copyright and protected information).

There have been numerous reviews and inquiries in recent years examining aspects of IP rights arrangements in Australia. This submission is consistent with those made by Health to previous reviews and inquiries, including in particular:

- the 2015 consultation on the Proposed Examination Practice following the High Court's decision in *D'Arcy v. Myriad Genetics Inc.* by IP Australia;
- the 2013 consultation on an Objects Clause and Exclusion from Patentability by IP Australia;
- the 2013 Productivity Commission Inquiry into Compulsory Licensing Report;
- the 2011 Senate Patent Amendment (Human Genes and Biological Materials Bill 2010) Report;
- the 2011 Advisory Council on Intellectual Property's Patentable Subject Matter Report;
- the 2010 Senate Gene Patents Report; and
- the 2004 Australian Law Reform Commission's Report No. 99, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99 Report).

In responding to the matters raised in the Issues Paper, Health aims to accommodate a balance of public and private interests to support the healthcare needs of the Australian community, and encourage commercial health sector interests to maintain investment in effective healthcare innovations to improve health outcomes.

2 Assessing the IP framework

One of the specific matters raised in the Commission's Issues Paper is the need to strike the right balance between private and public rights, particularly in the health sector where there is significant potential for adverse social consequences including access restrictions, higher prices and reduced choice or competition.

The Commission proposes a set of principles (effectiveness, efficiency, adaptability, and accountability) as a framework to guide its assessment of the IP system.¹ Health supports this framework as an objective tool to assist the Commission to assess how well Australia's IP framework is meeting contemporary community expectations. Health also suggests that, within these principles consideration should be given to how well the IP system, as part of the laws that belong to Australians, reflects the views of the public and community values.

We note that one of the key challenges in undertaking systematic reviews of the IP framework is ensuring that genuine community consultation and engagement is achieved, rather than consultation that only focuses on professionals, experts or businesses as end users of IP, who may be seen as the key stakeholder of the IP systems and are often best placed and resourced to make submissions to such consultations. While we welcome this inquiry and its overarching objective, the longer-term approach to the development and implementation of IP policy in the institutional landscape, however, is less clear.

The Commission acknowledges that the development of IP policy is a shared responsibility.² IP Australia is identified by the Commission as being the key institution responsible for administration of laws relating to patents, trademarks, designs etc., as well as being the lead institution responsible for opposition proceedings and the development and provision of policy advice, with support from other Commonwealth departments.

The independence of policy development from the administration and enforcement of regulation is an important principle in ensuring that regulators can maintain the confidence and trust of the community.³ As the granting of IP rights is a regulatory activity, this principle is important to ensuring that Australia's IP arrangements strike an appropriate balance for IP holders, IP users and the public interest. This was recognised in the 2010 Senate Community Affairs References Committee inquiry into

¹ Productivity Commission 2015, Intellectual Property Arrangements, Issues Paper, Canberra, p. 8.

² Productivity Commission 2015, Intellectual Property Arrangements, Issues Paper, Canberra, p. 25-26.

³ The Organisation for Economic Co-operation and Development (OECD) 2014, The Governance of Regulators, OECD Best Practice Principles for Regulatory Policy, OECD Publishing.

<http://dx.doi.org/10.1787/9789264209015-en>

gene patents which recommended the establishment of a patent audit committee to act as an independent source of credible advice to guide and inform the Government's engagement with the patent system.⁴

Previously, the Advisory Council on Intellectual Property (ACIP) provided independent policy advice to Government on intellectual property matters and the strategic administration of IP Australia. Despite a commitment to consider varying its membership to ensure that community/consumer, industry and research interests were sufficiently represented in response to comments and recommendations made in 2010 by the Senate Community Affairs References Committee, ACIP was abolished in April 2015. ACIP's website advises that 'reviews of IP Matters will be coordinated by IP Australia in the future'; however, it is unclear how the independence of policy advice will be maintained under this arrangement.

3 Patents

The Commission notes throughout its Issues Paper that IP, particularly the patent system, is a driver of innovation in the pharmaceutical and biotechnology sectors.⁵ Given this, Health has a strong interest in ensuring the effective and efficient operation of the patent system due to the direct budgetary implications on Australian Government programmes, the implications of competition in the health sector on the affordability of, and access to health products more broadly, as well as the implications for research and development.

Pharmaceutical IP has a significant influence on the cost of the Pharmaceutical Benefits Scheme (PBS), the programme through which the Australian Government subsidises the cost of listed pharmaceuticals. In 2014-15, the Government spent more than \$10 billion on the PBS, including \$5.3 billion on high technology products which are not subject to competition, in most cases due to patent protection. Industry estimates that a significant proportion of the value of a pharmaceutical product lies in its IP which, by extrapolation, also suggests that a significant proportion of PBS expenditure is effectively driven by IP rights where pharmaceuticals are protected by patents.

Researchers are able to obtain IP rights over research findings funded by public monies. Tax-payer funded inventions may then be licensed to companies who may subsequently defray licensing costs onto patients, government funded programmes or insurance

⁴ Senate Community Affairs References Committee 2010, Inquiry into gene patents. http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/genepatents43/index

⁵ Productivity Commission 2015, Intellectual Property Arrangements, Issues Paper, Canberra, p. 17.

companies.⁶ Some research funding agencies, therefore, require grantees to agree to meet certain IP management guidelines as a condition of funding. In the US, for example, recipients of publicly funded government research grants must grant the US Federal Government a limited use license to the invention. Alternatively, the US government may require an option to purchase a product (based on government funded IP) at cost minus any royalties. It may, therefore, be beneficial for the Commission to consider whether the balance between public and private interests is being achieved in relation to the commercialisation of products resulting from publicly funded research.

Previous reviews and inquiries have considered a number of actions to strengthen the patent system in the interests of all stakeholders. In 2011, ACIP recommended a number of reforms to the *Patents Act 1990*, including introduction of an Objects clause and an '*ordre public*' or morality exclusion from patentability. In addition, ACIP recommended that the definition of patentable subject matter be redefined. Health continues to support these recommendations, which were accepted by Government in November 2011⁷, as technology-neutral reforms that would improve the overall operation of the patent system.

Introduction of an Objects clause setting out the underlying purpose of the patent system and reflecting both its social and economic objectives would assist in the interpretation of the *Patents Acts 1990*, both in day-to-day practice, and where there is ambiguity or uncertainty. An *ordre public* or morality exclusion would provide flexibility to the Commissioner of Patents and/or the judiciary to decline the grant of a patent where its exploitation would not meet the expectations of the Australian community.

Amending the definition of 'patentable subject matter' in section 18 of the *Patents Act 1990* in clear and contemporary language would provide certainty to all stakeholders, including the community, researchers and the biotechnology and pharmaceutical industry sector. It also presents an opportunity to consider the broad implications of relevant Australian Court decisions, such as the decision in *D'Arcy v Myriad*⁸, and to implement their principles in legislation.

Other pending reforms that would improve the operation of the patent framework include amendments to the Crown Use and compulsory licensing provisions. In 2012, the Commission reviewed the operation of these provisions to ensure that they achieve

⁶ McKernan KJ, Spangler J, Helbert Y, Zhang L, Tadigotla V, 2013, Dreaming of a patent-free human genome for clinical sequencing, *Nature Biotechnology*, 31(10): p. 884-887.

⁷ Australia Government 2011, Response to report of the Senate Community Affairs References Committee on Gene Patents.
http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/genepatents43/index

⁸ *D'Arcy v. Myriad Genetics Inc* [2015] HCA 35 (Case No. S28/2015).

their intended purpose as safeguards to facilitate access to innovations where the reasonable requirements of the public are not being met.⁹ The Commission recommended that Crown Use provisions be amended to clarify its application, with particular regard to the scope of the entities that may exercise these provisions, and to improve transparency and accountability around their exercise.

We also note that the Commission has raised a recent recommendation relating to Australia's patent term extension (PTE) provisions which arose from the 2013 independent review of pharmaceutical patents.¹⁰ The PTE provisions provide for an extension of up to five years to compensate for the time it takes to obtain marketing approval of a pharmaceutical, and to provide greater market certainty and thus drive investment in pharmaceutical research and development in Australia.¹¹ While this incentive is provided under the *Patents Act 1990*, the effects of the provision are borne by the health system broadly, and by government pharmaceutical budgets in particular, due to consequent delays in the market entry of lower-cost generic pharmaceuticals.

The review recommended that the 'effective' patent term conferred by the PTE provisions should be reduced. Health agrees that this recommendation should be considered as part of the Commission's work. In this light, we note that the Government has committed to a range of measures to improve the overall business environment for innovative pharmaceutical research and development. The Government has also received two extensive independent reports reviewing the regulatory framework for medicines and medical devices which contain a number of recommendations for further reforms. Where such reforms lead to faster marketing approval of new pharmaceutical products, reliance on PTE by pharmaceutical patent owners should be reduced (so long as marketing approval for products is sought in a timely manner), and the effects of PTE (and any potential reforms to PTE) on the health system will be attenuated.

⁹ Productivity Commission 2013, *Compulsory Licensing of Patents*, Inquiry Report No. 61, Canberra.

¹⁰ Harris, T., Nicol, D., Gruen, N. 2013, *Pharmaceutical Patents Review Report*, Canberra.

¹¹ Commonwealth, *Explanatory Memorandum, Intellectual Property Laws Amendment Bill 1997*.

4 Data protection

Although data protection is recognised by the Commission as a form of IP right, consistent with both the World Trade Organization and the World Intellectual Property Organization^{12,13,14}, it was not included in the Commission's comparative analysis.¹⁵ Given that both patents and data protection are extensively used to protect new pharmaceuticals from competition, it is Health's view that comparative analysis and consideration under the Commission's proposed assessment framework would be useful to the broader consideration of Australia's IP framework.

Australia provides for five years statutory protection for confidential information (such as clinical, safety and efficacy data) submitted to the Therapeutic Goods Administration (TGA) by companies seeking marketing approval for a new medicine. In contrast, patents are granted for 20 years which, as discussed above, may be extended by up to five years for pharmaceuticals. While patent term and data protection commence at different points in the life-cycle of a pharmaceutical product, in most cases, they have a period of overlap. They are also provided in the same manner to traditional 'small molecule' pharmaceuticals and to so-called 'next generation' pharmaceuticals, biologics.

Aside from their duration, there are other significant differences between patents and data protection that have potential implications for pharmaceutical innovation and the interests of the community more broadly. In contrast to patents, data protection is an automatic right (i.e. no application is required or assessed), nor is the protection reviewable or contestable via administrative or judicial processes. In addition, whereas the grant of a patent requires full disclosure of the invention (as a measure to balance the monopoly rights against society's desire to promote follow-on innovation), data protection requires that protected information be kept confidential for the duration of the protected period.

As the Commission notes, there has been increasing debate over proposals for reform to data protection with industry lobbying to expand the scope of data protection to a broader range of products (including low risk over-the-counter and complementary medicines), for new uses of pharmaceuticals already available in the marketplace, and to increase the duration of protection beyond five years. Industry posits that such reforms are necessary as patent protection is not always available. While Health is

¹² World Trade Organization (WTO) 1994, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

¹³ World Intellectual Property Organization (WIPO) 2004, Intellectual Property Handbook: Policy, Law and Use. <http://www.wipo.int/about-ip/en/iprm/>

¹⁴ WIPO 2013, Trade Secrets: The other IP right, WIPO Magazine, No. 3. http://www.wipo.int/wipo_magazine/en/2013/03/

¹⁵ Productivity Commission 2015, Intellectual Property Arrangements, Issues Paper, Canberra, p. 5.

aware of a small number of examples where new pharmaceuticals have come to market with little to no patent protection remaining, persuasive evidence that this results from a failure of the patent system rather than other factors such as a business decision or oversight, has not been forthcoming.

Industry has also argued that recent judicial rulings have narrowed the scope of patentability, particularly in the biotechnology sector¹⁶, and an increase in data protection is required as a consequence. As the Commission notes however, in a balanced IP system it is not desirable to promote substitution between different IP rights¹⁷ and Health considers this is particularly true where the judiciary has determined that a thing is not innovative.

The countervailing argument, often advanced by public health representatives and the popular media, claims that strengthened data protection arrangements will increase the cost of pharmaceuticals. While such reforms are unlikely to directly increase the shelf price of an individual pharmaceutical, they do have potential to delay market entry of generic pharmaceuticals which often represent a more affordable choice for both public and private purchasers. The Commonwealth uses savings earned from the market entry of lower-cost generic medicines to assist in paying for the listing of new pharmaceuticals on the PBS. It follows that a delay in realising savings will lead to an overall increase in annual operating costs for the PBS, and/or a delay to the listing of new products.

To date, the debate around data protection has been relatively binary. Health considers that data protection is one policy lever in the broader suite of innovation system tools that are used by governments to promote research, development and commercialisation of innovative technologies, including pharmaceuticals. Australia's data protection arrangements carefully balance the commercial dynamics of Australia's domestic pharmaceutical market, public health policies and international obligations and, as such, cannot be simply compared to the arrangements for other sectors (e.g. agriculture), or jurisdictions.

Maintaining a balance between innovation and public health policies and programmes is critical to ensuring the future sustainability of our public health system. Health holds the view that any reviews considering reform to Australia's data protection arrangements must consider empirical evidence of a systemic market problem, modelling of the effects of any proposed reforms, and the potential role of other relevant policy levers, including balancing provisions (e.g. public disclosure of protected information). A debate that focuses on strengthening one IP right, without careful

¹⁶ This includes the 2013 ruling of the Supreme Court of the US in *Association of Medical Pathology et al v. US Patent and Trademark Office et al* (Case No. 12-398) and the 2015 ruling of the High Court of Australia in *D'Arcy v. Myriad Genetics Inc* [2015] HCA 35 (Case No. S28/2015).

¹⁷ Productivity Commission 2015, *Intellectual Property Arrangements*, Issues Paper, Canberra, p. 5.

assessment of the issue at-hand and due regard for alternative policy options that may be available across the broader innovation system, has significant potential to undermine the IP system and to result in adverse social consequences more broadly.

5 International agreements and fora

Australia is a signatory to multiple international agreements under which the Commonwealth has made certain commitments in relation to intellectual property rights and protections.

While Health generally considers that policy relating to IP protections relevant to the health sector are a domestic matter, we contribute to debate in international fora to ensure that any ensuing agreements strike an appropriate balance between ensuring the rights of IP holders and users, and to incorporate robust flexibilities to enable governments to legislate in the public interest.

When entering into international agreements Health works to ensure that IP protections do not limit our capacity to deliver significant public health programmes, including the PBS and tobacco control measures, in an efficient and sustainable way. Health advocates for strong safeguard measures so that vulnerable populations, particularly in least-developed and developing economies, can access safe and affordable healthcare technologies including vaccines. Additionally, in considering the public health risks of counterfeit health technologies, Health works with other jurisdictions to ensure that enforcement provisions are balanced and effective.

In recognising the importance of international trade and economic growth as contributors to improving health outcomes globally, Health contributes to a range of whole-of-government strategies and activities. This includes working closely with the Department of Foreign Affairs and Trade (DFAT) and other government agencies including IP Australia, the Department of Industry, Innovation and Science, the Department of Immigration and Border Protection, and the Attorney-General's Department, as required. DFAT's website provides information on concluded agreements and those currently under negotiation:

<http://dfat.gov.au/trade/agreements/Pages/trade-agreements.aspx>.