



## AusBiotech submission to the Productivity Commission Issues Paper on Australia's Intellectual Property Arrangements

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AusBiotech welcomes the opportunity to make this submission to the Productivity Commission following the issuance last month of its issues paper on Australia's intellectual property (IP) arrangements.

The following comments from AusBiotech are based on input from its Intellectual Property Expert Panel – an advisory panel made up of IP practitioners, in-house IP counsel and users of Australia's IP systems from AusBiotech's membership base. The comments are based on many years of working to grow Australia's strength in biotechnology and medical devices.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 500 – 900 medical technology companies) and employs in excess of 45,000 Australians.

The 500+ medical device companies in Australia, with a few exceptions are typically young and small, competing globally with large multi-national companies for market share. The industry is advancing rapidly into new fields of science and engineering, with nanotechnology and other research developments facilitating new innovations in the biomedical sphere and an increasing convergence of physical and biological technology platforms. It is a highly innovative sector pushing the boundaries in advanced manufacturing, using highly skilled labour distributed to global production chains and specialised markets.

Intellectual property is the fundamental source of protection for these innovations. It is particularly important that local innovation is not disadvantaged through a lack of harmonisation with other region's IP systems. Ensuring that Australia has a globally competitive IP system is the key to our future health and wealth. Such a system will help:

- increase the return on inventions and developments made possible by the significant level of public support for medical research in Australia;
- provide greater incentive and certainty for the commercialisation of local, Australian health technology inventions and developments – supporting Australia's rapidly developing biotechnology sector;
- attract additional global investment in Australia's research and development efforts; and
- increase access to new medicines, medical devices and vaccines for Australian patients.

Given the importance of harmonisation, AusBiotech considers that extreme care must be taken before seeking to modify Australia's existing approach to IP protection.

AusBiotech is strongly of the view that Australia's existing IP arrangements do not unduly limit the diffusion of knowledge. Indeed, the current system is supportive of such diffusion as the filing of patent applications serves to ensure diffusion of knowledge that might otherwise be retained as a trade secret or never utilised in the public domain.

AusBiotech supports Australia having an efficient and effective IP system. Such a system must balance the needs of innovators and third parties. Users of the IP registration systems must have confidence that the IP rights awarded are likely to be held valid in any subsequent court assessment. IP Australia plays an important role in ensuring this confidence and it is important that that body retain the skills and resources necessary to examine and award patent and other IP rights in Australia. While international harmonisation is important, the role of IP Australia as the gatekeeper of establishing registrable IP rights in Australia should not be diminished.

Australia has traditionally been considered to have a patent system that was sufficiently flexible to accommodate changes in technology. The recent decision (October 2015) of the High Court of Australia in

D'Arcy v Myriad Genetics has challenged that view and also seen Australian practice diverge from that seen in Europe and many other countries. It is too early to determine the full impact of this decision but AusBiotech does anticipate that it will ultimately be necessary for the legislature to re-visit the definition of what might be considered "patentable subject matter" in Australia to promote certainty.

Without further detail, AusBiotech does not support the notion that introducing "economic criteria" for patentability would improve the efficiency and effectiveness of the patent system. How IP is funded should also not impact the duration of patent protection and further, the capacity for IP Australia to make a determination of the economic impact of IP would fall outside their core area of expertise.

Design rights can and do play an important role in certain industries. It is AusBiotech's view that the design rights term in Australia should be reviewed and brought into alignment with that of Australia's major trading partners. It is considered that design applications should undergo substantive examination prior to "grant".

Concerning some specific questions posed in the Issues Paper, AusBiotech makes the following comments.

### **Are IP rights too easy or hard to enforce in Australia, and if so, why?**

Based on our understanding and experience, Australia sits somewhere in the middle of the spectrum between countries where IP enforcement is quicker and cheaper but still seen as broadly fair (an example being Germany) and countries where the court systems are dysfunctional to the point where enforcement of any legal rights are problematic. Leaving aside general differences among legal systems, Australia is probably towards the reliable of the spectrum in that IP rights are not generally regarded by the courts as inherently suspect or illegitimate (although the High Court's recent Myriad decision causes concern in this regard, to the extent that there is a suggestion that suspicion of patent rights in an area of technology by a sector of the public, may be regarded by the courts as a reason not to permit patents in that area of technology).

Like other common law jurisdictions, litigation in Australia takes a long time, is expensive, and has less focus on cost effectiveness and efficiency. Given the size of the Australian market for many patented technologies, the value of pursuing an enforcement action in Australia is often viewed by domestic and international companies as too low. AusBiotech acknowledges that many of the factors that underlie the higher costs within Australia's IP system relative to equivalent regulatory systems are due to the comparative market sizes. Recognising these limitations AusBiotech supports and encourages the Commission to pursue measures that provide for a more efficient enforcement system with the proviso that these measures do not undermine, and preferably enhance, the strength of IP rights in Australia.

### **To what extent can Australian firms enforce their IP rights internationally? Does this differ across regions and/or countries?**

It is inevitable that there will be variation in the ease with which IP rights of Australian firms can be enforced internationally across regions and/or countries. All Australia can reasonably ask for is that, in the context of an overseas jurisdiction, Australian firms are not discriminated against and are treated equally with local firms (and that the laws of the overseas jurisdiction comply with international treaty obligations). Australia should continue to actively support international efforts encouraging transparency and strong enforcement of valid IP rights internationally.

### **Which features of the current enforcement system work well, and which could be improved?**

AusBiotech supports a system that competently and efficiently examines applications for obtaining an IP right, and that is efficient and predictable to enforce once it is obtained. Particularly in the case of patents, rigorous examination of patent applications coupled with a presumption of validity once a patent is granted, makes for a respected patent system when done well. A patent system that sets a relatively low

bar for the grant of patent, resulting in enforcement litigation in which many or even most granted patents are found by the court to be invalid and therefore unenforceable, is less likely to be taken seriously by markets and potential infringers. It not only leads to uncertainty because many granted patents are known to exist, but are suspected to be invalid and unenforceable, it also wastes valuable resources of the government and companies in an often long and expensive process. This is also true for the Australian Innovation Patent system, whereby Innovation Patents are granted without undergoing examination and only require a very low threshold of inventiveness. This leads to discrimination based on available economic resources, as firms with fewer resources may find themselves constrained by patents that they suspect are invalid, but which they do not have the resources to challenge. That said, Australia's relatively recent 'Raising the Bar' reforms were intended to deal with this issue, and to some extent have done so.

Returning briefly to the High Court's recent Myriad decision, this decision does give rise to the potential for a general weakening in the enforcement of patents for inventions in new fields of technology. The majority decision states that:

*"The proposition that a broad statutory concept applies to a new class of case on the boundaries of existing judicial development of that concept requires consideration of the limits of judicial law-making inherent in common law methodology. Where an affirmative application of the concept is likely to result in the creation of important rights as against the world, to involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination. The patentability of nucleotide sequences derived from human DNA is in that category. The inherent patentability of the invention as claimed would powerfully imply patentability of any claim for an isolated nucleic acid coding for a specified polypeptide."*

This seems to suggest that Australia is moving from a patent system in which uniform principles are applied as new technologies arise and evolve, to a patent system in which, for every new technology, the courts will be required to make a subjective determination as to whether patenting will "involve far-reaching questions of public policy" or "affect the balance of important conflicting interests", in which case patentability must be denied unless and until the legislature intervenes to apply existing and accepted principles of patent law to the new technology. This type of system is undesirable and raises the prospect for unpredictable and counter-productive future developments of Australia's patent system that discourages investment.

### **Is Australia's enforcement system well balanced, or weighted in favour of one group?**

Generally speaking, AusBiotech considers Australia's IP enforcement system to be well-balanced. Valid IP rights can be enforced, and invalid IP rights can be proved invalid, with relatively equal fairness and predictability, however it is at a level of expense, which is relatively high by global standards given the size of the market but within the norm for common law jurisdictions.

### **What improvements could Australia adopt from overseas approaches?**

In the context of IP, Australia generally gets it right within a larger common law system, although legitimate criticisms can be made of the length and expense of inquiries, in particular compared with the inquisitorial Continental European approach, which appears to secure reasonably just outcomes in civil disputes at a fraction of the cost. We would also recommend an extension of the data exclusivity period in Australia as it relates to therapeutic goods, and specifically biologics (see below). It would be good to see Australia adopt procedures in the IP (and particularly patent) context that seek to streamline the process either through administrative proceedings and/or court processes being considered in other common law jurisdictions.

## **How does Australia's current protection of regulatory test data affect innovation and the diffusion of new products?**

The delivery of therapeutics to the community as life-saving and enhancing medicines requires the attraction of significant investment. The length of intellectual property (IP) protection, such as patent life and data exclusivity periods, is a criterion that influences investing decisions in Australian biotech companies.

Investors will attest that intellectual property is at the core of any life sciences company valuation, and as such, the life of the patent and the data exclusivity once a company gets their product to market is of paramount importance when assessing which companies they will invest in. Anything that shortens the period of protection places significant downward pressure on the valuation of a company, and thus decreases its attractiveness for investment. The period of IP protection is an essential factor in determining the value of the investment as it is the main opportunity to recoup an investment in research.

AusBiotech has for many years been encouraging direct foreign investment into life sciences companies and harmonising the period of protection with our main trading partners, in particular the USA, would be advantageous for Australian companies.

Australian patents provide a formal 20 years of protection to certain types of pharmaceutical inventions (or longer if an extension of term is granted). However, the average effective patent life for these products in Australia is between 11 and 12 years. This is because it typically takes around 10 years, and sometimes longer, to bring new a pharmaceutical product to market, after a patent registration. As this time between patent registration and market approval lengthens, the formal protection (and therefore the invention's value) becomes less and less. While data exclusivity runs independently from a patent protection period and often concurrently, it plays an important role in the situation where a patent has almost (or has) lapsed by the time regulatory approval is sought or where no or poor protection is available due to the type of technology. For example, in the area of biologics where the 'method of manufacture' is the focus of the IP rather than a molecule, nuances of protecting biologic IP is greatly complicated, in some cases making patents alone inadequate for safeguarding this IP.

To maintain a reasonable level of protection the system needs to be updated from time to time. At the moment, this need for reform applies to Australia's provision of data exclusivity, a niche but critical component of our intellectual property system.

Australia's five-year data exclusivity provision lags global competitors and collaborators such as the United States (up to 12 years), Canada (eight years), the EU (up to 11 years), Japan (eight years) and even countries like Russia and China (six years). This puts at risk investment in Australia's rapidly growing domestic pharmaceutical and biotechnology sectors.

Among other reports, we note that the 2013 "Strategic Review of Health and Medical Research in Australia" (the McKeon Review) called upon the Federal Government to extend the term of data exclusivity to harmonise an important element of the Australian IP system with global best practice. We also note that the Australian Parliament recently granted, without controversy, data protection to veterinary medicines for companion animals, namely medicines for Australia's dogs, cats and other pets. The level of protection went from zero to ten years. That is twice the level of intellectual property protection provided to new cancer medicines and other medicines - for humans - that rely on data exclusivity.

AusBiotech appreciates the opportunity to provide these comments and looks forward to engaging with the Productivity Commission as the Inquiry continues through 2016.