



**AusBiotech response to the
Productivity Commission's Draft Report:
Intellectual Property Arrangements
(April 2016)**

To: The Productivity Commission
Inquiry into Intellectual Property Arrangements
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Introduction

AusBiotech provides this submission in response to the Productivity Commission's Intellectual Property Arrangements Draft Report (April 2016), after also making a submission to the Issues Paper on Australia's Intellectual Property Arrangements (November 2015).

AusBiotech is a network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 30 years to provide representation to promote the sustainability and growth of Australian biotechnology.

The industry consists of an estimated 900 biotechnology companies (400 therapeutics and more than 500 medical technology companies) and employs in excess of 45,000 Australians.

In Australia, with a few exceptions, these companies are typically young and small, competing globally for investment and 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 and creates value that is used to attract the substantial, often multi-million dollar, investment it takes to bring these treatments, cures, tests and devices to the market. It is particularly important that local innovation is not disadvantaged through a lack of harmonisation with other region's IP systems. With innovation in medical technologies and (bio)pharmaceuticals recognised as one of Australia's comparative strengths, the industries have importance for the transition of the Australian economy and social fabric. Therefore, ensuring that Australia has a globally competitive IP system that enables development of new biotechnologies is the key to Australia's future health and wealth.

Please find following AusBiotech's comments, based on feedback from its membership, which includes biotechnology and medical technology companies, ranging from start-ups to mature multinationals, research institutes and universities, and specialist service professionals, including patent specialists.

Comment on the overall analysis

Many of the recommendations made in the Commission's Draft Report appear to be revisiting issues and past proposals that have already been given detailed consideration and in some case stand-alone reviews and inquiries. In addition, many of the issues raised in the Report were raised in the period leading up to the implementation of the "Raising the Bar" Act in 2013, which raised the quality of granted patents to more closely align Australia patentability standards with international standards and enshrined a broad research use exemption so this country's researchers and industry may be confident as they strive to innovate.

The findings of this Review are reminiscent of those in the Pharmaceutical Patents Review (2013), which drew a visceral negative response from the local and global research-based biopharmaceutical sector.

“The one practical outcome of this report is that it further entrenches the 'vibe' against pharmaceutical patents in Australia...,” said Editor of Biotech Dispatch, Paul Cross.

Suggested abolition of innovation patents

AusBiotech does not support the abolition of the Innovation Patent system and finds the recommendation to abolish the system is premature, without proper consideration of alternatives. AusBiotech would, however, support analysis of alternatives that would improve the Innovation Patent system in three key areas: raising the innovation threshold; requiring examination prior to grant; and setting an examination deadline.

Any changes ought to be properly explored with stakeholders and should provide additional opportunity to consider the merits or otherwise of any proposed changes. In particular:

- With appropriate modification, the Innovation Patent system can meet the needs of Australian innovators – particularly, but not limited to, those of small and medium enterprises.
- The threshold for an innovative step of an Innovation Patent should be raised.
- Unexamined Innovation Patent applications should remain pending until an examination has been completed and the application accepted.
- All Innovation Patents should be examined within a defined period. Three years is considered to be an appropriate maximum time for examination.
- Australia should retain a second-tier or lower-innovation-threshold patent system.

Objects clause

The recommendation to introduce an objects clause is of concern. Discourse and reviews in this regard has been ongoing for more than a decade and AusBiotech has made previous submissions on proposed options. There has been no option proposed to date that appears to be practically workable and there remains no compelling rationale articulated, to move away from the language of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).

AusBiotech has a preference that any clause proposed remains consistent with the TRIPS wording: *“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”* (Agreement on TRIPS, Article 7, ‘Objectives’)

Biotechnology is a global industry and the extent to which the already complex web of patent laws and provisions can be harmonised globally, is substantially more helpful for technology developers to traverse.

The Commission identified two values to address with an objects clause: the idea that inventions be “socially valuable” to warrant being patent eligible, and that only “additional” IP should be eligible for a period of protection.

It is unclear how the objects clause would or could be applied. This proposal has the potential to

create substantial uncertainty and greater burden for patent examiners, who may be tasked with making decisions about a patent's public interest, and applicants, who may be in the position of having to divulge commercially sensitive information to the Patent Office.

It may also lead to litigation to determine the parameters around what is "socially valuable", adding cost time and not necessarily achieving a clear outcome.

Furthermore, the proposal that patents should not be granted for inventions that would have been made in the absence of patent protection, seems to misconceive the purpose of the patent system in encouraging and incentivising innovation. It is not claimed that patents are necessary for humans to be innovative; inventiveness is a natural human characteristic. But in a market economy, an invention will generally not benefit humankind unless and until it is turned into a product or process that can be commercially supplied. It is mostly this aspect of innovation – the creation of a saleable product or process out of an invention – that is incentivised by the patent system. It may be true to say that a person would have thought of an idea even in the absence of patent protection, but that in no way establishes that the idea would benefit humanity in the absence of a commercial incentive in the form of a temporary legal monopoly, allowing for the cost of necessary commercial development of the idea to be recouped.

Patent extensions

Extensions to patent life for health technologies like pharmaceuticals are important because the regulatory and reimbursement processes consume years of patent life - and the period or the possible period of the patent influences the decisions of investors.

While the fledgling and emerging Australian biotechnology industry is doing well, it has struggled to deal with the aftermath of the global financial crisis – having contracted from 128 ASX-listed companies in 2008 to 112 in 2009 ASX-listed companies, and now holding steady at about 90. The sector is especially vulnerable to shifts in government policy. The industry faces a number of persistent issues; raising funds and attracting investment remains an ever-present problem for smaller (pre-revenue) companies, but is even more critical when the fiscal environment is challenged. The only asset is often IP and if this proves to be less secure, the temptation will be to lodge patent applications in other jurisdictions.

If these small companies, which are predominantly progressing therapeutics, are to be successful in reaching the market (and earning revenues), and therefore able to contribute back to the Australian economy, they do not need any further government policy changes that act as a disincentive or barrier to attracting investment. AusBiotech contends that the removal or reduction of the patent extension term, will impact investment decisions and make the attraction of investment even harder than it is now. While the patent term extension is obviously not the only factor on which an investor will make a decision, the total term available does in fact influence the risk profile and affect decisions.

Of the eight major companies actively providing venture capital to Australian biotechnology companies, GBS Venture Partners and BioScience Managers are significant investors. Both agree that the proposed changes to patent extensions will make Australian medicine developers less attractive to investors.

Brigitte Smith, Co-founder and Managing Partner of GBS Venture Partners, said: “A reduction in patent life in Australia would be a criterion that would negatively influence our interest in investing in Australian biotech companies. Often we look at companies that are developing therapies for diseases that are particularly prevalent in Australia (such as melanoma, or lesser skin cancers). If the patent life is shorter in Australia than it should be, that would make it less attractive to invest overall.”

“Once we have made an investment, the fact that Australian patent life is shorter than it should be would negatively affect our decision to commercialise in Australia, which would be a disappointing outcome. If R&D is paid for by the Australian people, I would hope that Australia would be a high priority for commercialisation of the resultant therapy, but if the patent life is shortened it becomes less attractive to do that.”

Jeremy Curnock Cook, Managing Director of BioScience Managers said: “Intellectual property is at the core of any life sciences company valuation. As such, the life of the patent and the market exclusivity once a company gets their product to market is of paramount importance to us when assessing which companies we will invest in. Anything that shortens this period of market exclusivity places significant downward pressure on the valuation of a company, and thus decreases its attractiveness for investment.”

Data exclusivity provisions

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, which requires a higher level of investment, risk and time in development.

Harmonisation with international standards

Australia's legal framework for pharmaceutical patents is not set exclusively by domestic law. The country maintains a number of international trade agreements, including TRIPS, the US-Australia Free Trade Agreement and the recently negotiated Trans-Pacific Partnership Agreement, to name a few.

These agreements clearly set out Australia's obligations in relation to many of the areas touched on by the Productivity Commission, including patent term extensions and data protection. The upshot is that any winding back from current law would trigger a 'hellfire' global response - not just from the US, but Japan and the EU.

While it's not out of the question that Australia might decide to walk away from its obligations under these international trade agreements, such a move would be unprecedented and almost certainly attract trade reprisals from other countries.

Changing "inventive step" standard

In response to the Commission's recommendation to amend the definition of an inventive step in Australia to bring it into line with the definition used in Europe, AusBiotech raises the question of when the analysis was conducted, before or after the 'Raising the Bar' legislation was enacted, and is this recommendation relevant since the changes took effect in 2013 to align with Europe.

AusBiotech Member, Davies Collison Cave, said in *Lexology* (May 2016): "Given the relatively short timeframe that the Raising the Bar Act inventive step provisions have been in force, it seems premature to propose that Australia makes yet further changes. It is arguable that we do not yet understand the full impact of the changes that have already been made."

"The Commission has also made several references to the principle that, in Australia, all that is required is a "scintilla" of invention, suggesting that a scintilla is too low. Unfortunately, they have misunderstood this principle which is intended to convey the idea that once the inventive step bar is set, an invention is either inventive or it is not."

Conclusion

AusBiotech does not agree that the Innovation Patent system should be abolished, and instead proposes serious consideration be given to improving the system. Nor does AusBiotech agree that the objects clause proposed is suitable or that patent extensions should be decreased. AusBiotech supported the 'Raising the Bar' Act and would like to see it given time to settle and its impact properly assessed before further changes are considered.

AusBiotech supports an extension to data exclusivity periods for biologics and an efficient and effective IP system for Australia, which balances 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.

The balance required here and the real patient impact is likely to make it harder for biotechnology companies to develop and deliver new medicines in Australia, and further challenge the sustainability and growth of the emerging Australian biotech industry. In short, these changes recommended by the Productivity Commission, could have a negative impact on social value.