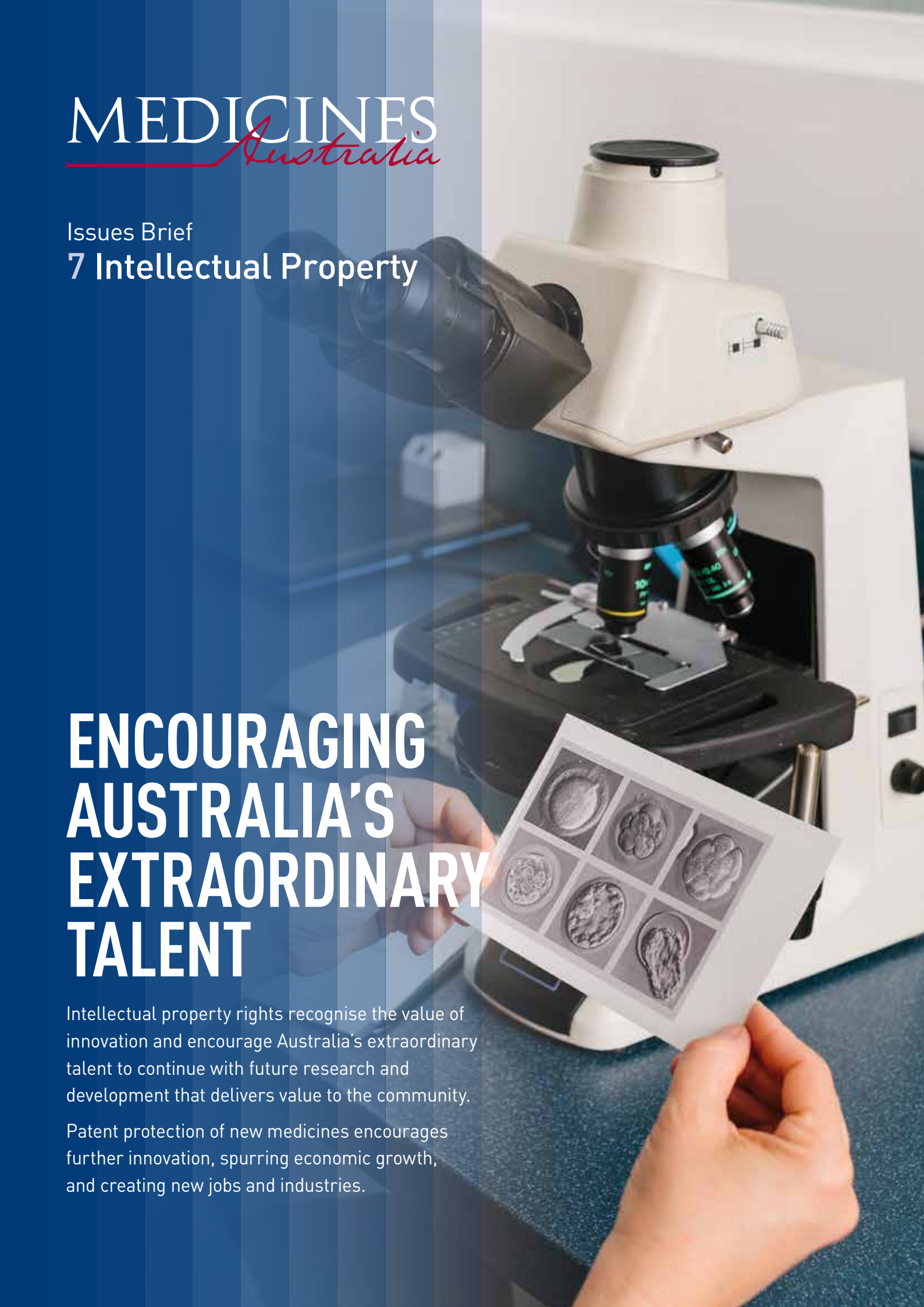
MEDICINES Australia

Issues Brief

7 Intellectual Property



ENCOURAGING AUSTRALIA'S EXTRAORDINARY TALENT

Intellectual property rights recognise the value of innovation and encourage Australia's extraordinary talent to continue with future research and development that delivers value to the community.

Patent protection of new medicines encourages further innovation, spurring economic growth, and creating new jobs and industries.

OBJECTIVES BRIEF 7:
INTELLECTUAL PROPERTY

Medicines Australia strongly supports the Australian Government in:

Encouraging innovation and investment in, and by, the innovative medicines industry by maintaining a strong and stable intellectual property (IP) environment.

Supporting the development of new medicines to improve Australians' health by improving patent protection.

Increasing data exclusivity provisions to align with our international trading partners.

Key fact:

Australia's intellectual property system ranks **11th** out of **142** countries on the International Property Rights Index.

Source: as cited in Australian Trade Commission, A dynamic environment for clinical trials, May 2015

OVERVIEW

Australia has a strong and stable IP system, making it largely comparable to IP systems in Europe, the United Kingdom, and Japan (except for a few key areas where Australia lags behind).

The main laws and regulations that provide the basis for Australia's IP system are:

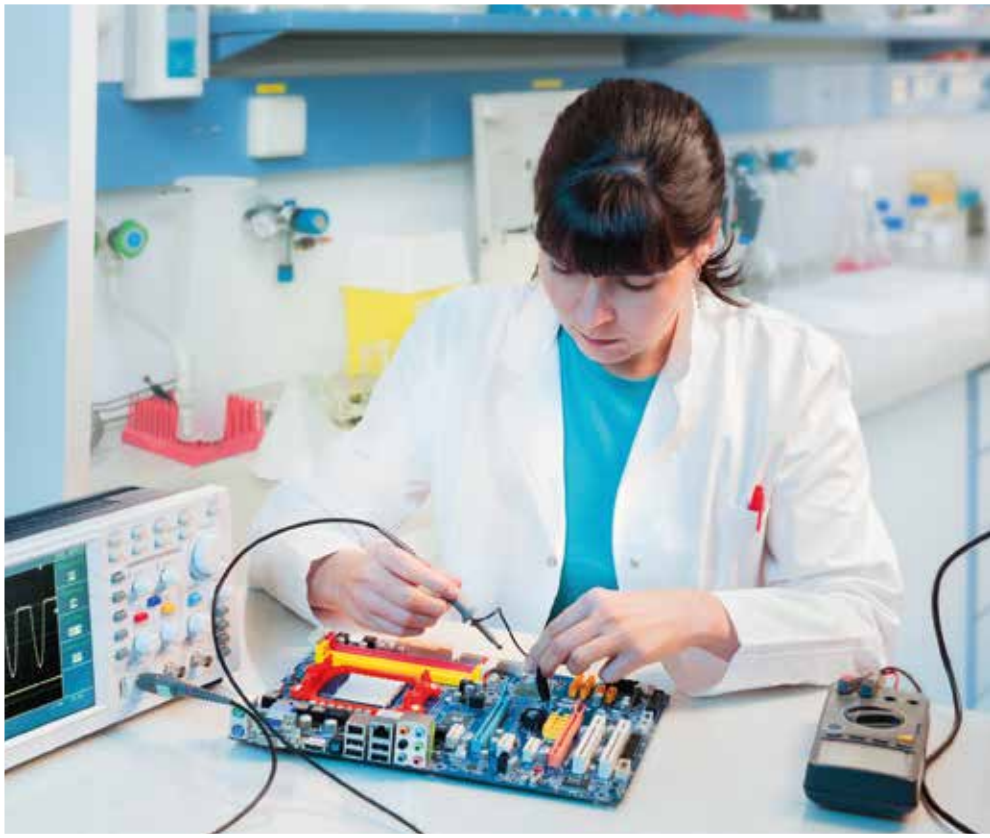
- Patents Act 1990 and Patents Regulations 1991
- Trade Marks Act 1995 and Trade Marks Regulations 1995
- Designs Act 2003 and Designs Regulations 2004
- Also, for pharmaceuticals, the Therapeutic Goods Act 1989

IP Australia is the public authority that administers most of the legislation within the Australian Government's portfolio of Industry.

The Patents Act 1990 provides an incentive for companies to incur the cost and risk of research by providing a time-limited exclusive right to market a product.

In 1999 the Australian Government introduced the right for pharmaceutical companies to seek "patent term restoration" – that is, the right to apply for up to five years of extension of patent term.

This measure can assist in ensuring up to 15 years of effective patent life is restored from the date of first entry of a product on the Australian Register of Therapeutic Goods (ARTG), which is administered by the Therapeutic Goods Administration (TGA). For technology industries, 15 years is considered a reasonable period to recoup the significant costs of investment and compensate for the upfront risks, however, in Australia, the average effective patent life for a new medicine is commonly only 12 years.



OVERVIEW CONT.

For technology industries, 15 years is considered a reasonable period to recoup the significant costs of investment and compensate for the upfront risks, however, in Australia, the average effective patent life for a new medicine is commonly only 12 years.

The reasons for granting the opportunity for patent term extension were to:

- Compensate pharmaceutical patent holders for delays in obtaining regulatory approval for new products
- Provide incentives for pharmaceutical companies to continue to invest in research and development (R&D) in Australia.

This right ensures that products in Australia can receive an effective patent term that is consistent with other international jurisdictions.

Operating in parallel to any patent term is a five-year period of data exclusivity, or Regulatory Data Protection (RDP), that commences at the time a new pharmaceutical product is entered on the ARTG. This period of RDP prohibits others from using or relying on the data generated by the innovative research company's clinical development programme, without having conducted any clinical research or borne any of the risks. RDP is particularly important for products where patent protection is not available or has expired, to compensate for the absence of patent protection by providing a data specific period of exclusivity during which to recoup investment. Data exclusivity generally expires some years before the patent.

Recently, as part of the Trans Pacific Partnership Agreement the Australian Government has included provisions by which RDP can be extended to 8 years for biologics.[1] This acknowledges that Australia has fallen behind other comparable countries. It is yet to be explained how this will be implemented in practice without changes to current legislation. Canada, Japan and the EU have a minimum of 8-years data exclusivity while the United States has up to 12 years for biologics.[2]

1. Chapter 18 of TPP Agreement. Article 18.52 states that effective market protection of undisclosed test or other data for a period of at least eight years.

2. Medicines Australia submission to the Productivity Commission Review of Intellectual Property Arrangements in Australia https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20151130-sub-PC-Review-IP-Arranagements-FINAL.pdf

CHALLENGE: MEDICINE DISCOVERY IS HIGH RISK

Key fact:

It takes an investment of US $1.5-2.6 billion[3,4] to support a medicine in its 10-15 year journey from discovery until it can be made available to the Australian public.[5]

Medicines investment is high-risk with approximately 12% of drugs that enter clinical trials reaching approval for use by patients.[5]

The research-based innovative pharmaceutical industry, like all research-based technology industries, relies on a robust patent system. Without IP protection there would be no incentive to invest in the high-risk R&D required to discover new medicines.

Generic medicines only exist because of innovative medicines. A generic medicine can be offered at a substantially lower price due to the fact that its manufacturer did not bear any risk, nor incur any of the expensive discovery, research and development costs. A generic medicine cannot enter the Australian market if the originator medicine has not firstly been assessed as safe and effective for marketing in Australia by the Australian regulator. It is appropriate that the IP system remains strong and stable to both create incentives for innovators to develop new medicines and to support Australian access to these new medicines as the generics of the future.

A strong, stable and predictable IP system is essential in supporting investment in new research for some of our most challenging diseases.

3. DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics 2016;47:20-33.

4. Mestre-Ferrandiz, J., Sussex, J. and Towse, A. (2012) The R&D Cost of a New Medicine. Office of Health Economics. https://www.ohe.org/publications/rd-cost-new-medicine

5. PhRMA, Medicines: Cost on Context. Available at: http://www.phrma.org/cost

FUTURE CONSIDERATIONS

Any further IP reforms should be undertaken after extensive consultation to ensure they are well targeted.

Medicines Australia welcomes acknowledgment from the Australian Government that our intellectual property system should provide appropriate incentives while not unreasonably impeding production.[6] During the term of the last parliament, a number of reviews, reports and consultation processes were commenced by government which relate to IP.

While there may be a need for the Australian Government to review IP laws from time to time, any future changes must involve extensive consultation to ensure they are well targeted. The changes to intellectual property laws made in the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 are still being implemented and the impact of these changes is yet to be fully realised.

The Joint Committee for Trade and Investment's parliamentary inquiry into Australia's future in research and innovation report provides a useful starting point for further dialogue. Medicines Australia has welcomed a number of recommendations suggested in the Joint Committee for Trade and Investment Committee's report that relate to IP. These recommendations build on those from the McKeon Review in 2013 which called for strengthening Australia's IP system to ensure that it appropriately encourages investment in R&D in health and medical research.[7]

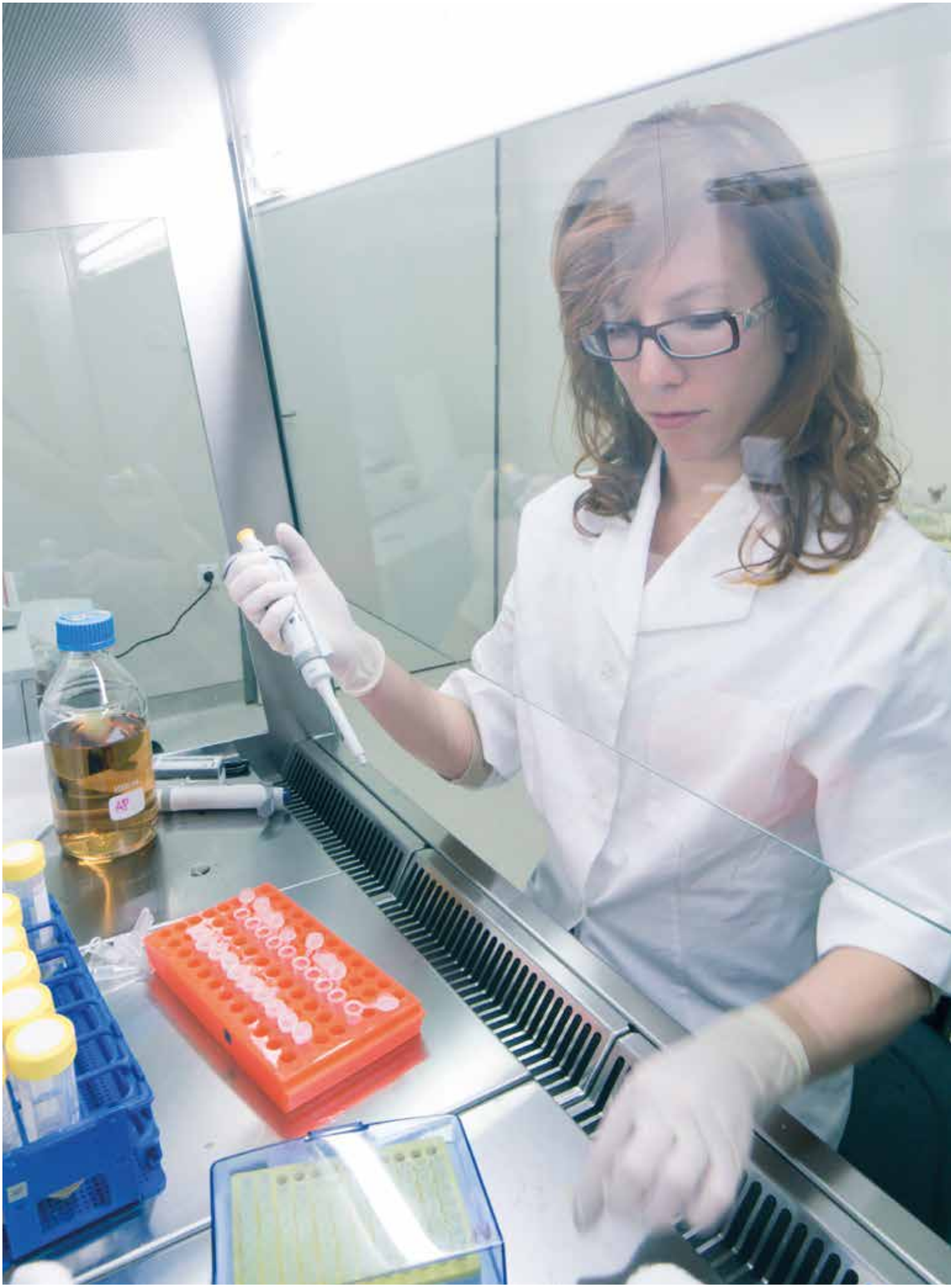
The Productivity Commission's current examination of Australia's IP system remains a high-stakes inquiry for the medicines industry. The incoming Government's response to the Productivity Commission report will be of critical importance, given the complexities of the issues.

Through Innovation and Science Australia (ISA), the Australian Government is understood to be working closely with IP Australia on the results of this inquiry.[8]

6. Liberal Party of Australia, Coalition response to Medicines Australia, Federal Election questionnaire, June 2016, unpublished

7. McKeon, S. et al 2013. Strategic Review of Health and Medical Research.

8. Bill Ferris AC, ISA Chair, March 2016, Research Excellence and commercialisation: How can Australia do both? Available at: http://www.industry.gov.au/Innovation-and-Science-Australia/Documents/Speech-UA-10-March-2016.pdf



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EXECUTIVE SUMMARY

A COMMON GOAL IN INTELLECTUAL PROPERY

An intellectual property system that provides appropriate incentives to innovate while not unreasonably impeding production.

KEY CHALLENGE

- Medicines investment is high-risk with approximately 12% of drugs that enter clinical trials reaching approval for use by patients.

KEY SOLUTION

- A strong, stable and predictable IP system that is internationally aligned is essential in supporting investment in new research for some of our most challenging diseases.

FUTURE CONSIDERATIONS

- Any further reforms to Australia's IP legislation should be undertaken with extensive consultation to ensure they are well targeted and continue to encourage investment in R&D in health and medical research.

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