BioMelbourne Network submission in response to the *Australian Patent Box: Treasury Discussion Paper on Policy Design (July 2021)*

16 August 2021

1. Executive Summary

BioMelbourne Network welcomes the Australian Government's announcement to introduce a patent box for corporate income associated with patented inventions in the medical and biotechnology sectors.

This submission summarises the key matters considered by BioMelbourne Network's members in assessing the proposed policy design for the Patent Box. A number of BioMelbourne Network members will be independently provide the Treasury with separate submissions setting out case studies or worked examples as to how the policy design of the Patent Box would likely affect their tax position in Australia.

BioMelbourne Network makes the following recommendations to Treasury:

(a) A concessional tax rate of no more than 10% should be considered to ensure Australia remains competitive amongst peer nations in attracting research, development, and commercialisation of relevant intellectual property rights in Australia.

(b) The Patent Box regime should be modelled on regimes in comparable jurisdictions, such as the UK and Ireland. The scope of eligible intellectual property rights should also be broadened to patents granted in other jurisdictions of comparable or equivalent systems as Australia.

(c) If the regime is to be limited to the medical and biotechnology sectors, the well-understood definition of 'therapeutic good' under section 3(1) of the *Therapeutic Goods Administration Act 1989* (Cth) (**TGA Act**) should be utilised, instead of the International Patent Classification (**IPC**) or the Cooperative Patent Classification (**CPC**). This definition would apply to the intended use of the relevant patented innovation.

(d) The requirement for patents to be filed after 11 May 2021 should be removed from the proposed eligibility requirements for the Patent Box regime. Instead, all patents in existence as at the start date of the Patent Box regime, i.e. 1 July 2022, should be eligible for the Patent Box regime.

(e) A substantial activity requirement should be applied to the Patent Box regime in Australia. Alternatively, the modified nexus approach should be considered, rather than applying the stricter nexus approach.

(f) Eligibility under the Patent Box regime should be assessed on a 'whole of product' basis, rather than on a patent-by-patent approach.

(g) The ATO assessment of offshore activities in the context of intellectual property rights should be considered, as it may better align with the incentivisation of the medical and biotechnology industry in Australia under the Patent Box regime.

Any defined terms used in our submission have the meaning given in our submission or are otherwise defined in the *Australian Patent Box: Treasury Discussion Paper on Policy Design (July 2021)* (**Discussion Paper**).

2. About BioMelbourne Network

BioMelbourne Network is an industry-led membership association for medical and biotechnology companies and organisations in the State of Victoria.

BioMelbourne Network's mission is to foster the development of an advanced, innovation driven and sustainable health industry. BioMelbourne Network seeks to achieve its mission by connecting business, research, finance, health and government to support and promote the industry's growth and facilitate the development and commercialisation of new drugs, devices, diagnostics and digital health technologies in Victoria.

We have a number of notable members. For this particular submission, we have drawn from the experience and expertise of a working group from Atomo Diagnostics, Cook Medical, CSL, Cochlear, Nanosonics, Polynovo, Prism Surgical, ResMed, and Saluda Medical.

3. Australian medical and biotechnology operating environment

3.1 Contribution to the Australian economy

The approximately 50 global research-based pharmaceutical companies and 400 locally-owned biotechnology companies[1] create high-wage and high-skilled employment in Australia. This economic benefit is created directly through research, manufacturing, marketing, sales and indirectly to other areas of the economy through goods and services.[2] In direct investment alone, these firms invested $1 billion into local research and development (**R&D**) for the 8 years leading to 2017.[3]

The economic contribution of medical and biotechnology firms to the Australian economy is enhanced through partnerships with Australia's medical research sector. 75% industry-funded clinical trials in Australia are conducted in partnership with public hospitals and private research institutes. In 2015, the clinical trial sector in Australia contributed approximately $1.1 billion to the Australian economy via direct expenditure or investment.[4] According to a 2011 survey, privately funded clinical trials are worth approximately $636 million in Australia each year.[5]

Most importantly, the medical and biotechnology industry helps save lives and improve healthcare outcomes in partnership with Australian governments, though initiatives such as the pharmaceutical benefits scheme. BioMelbourne Network is proud to acknowledge its members' contributions, and those of other industry participants, to this endeavour.

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[1] Medicines Australia, Facts Book 4th Edition (2015) <https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/MAFactsBook4_update2015.pdf> page 4.

[2] Medicines Australia, Facts Book 5th Edition (2021) <https://www.medicinesaustralia.com.au/wp-content/uploads/2021/06/Medicines-Australia-Facts-Book-2021.pdf> Chapter 6

[3] ABS statistics available at http://www.abs.gov.au/ausstats/abs@.nsf/mf/8104.0.

[4] MTP Connect, Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector, 2017.

[5] Pharmaceuticals Industry Council, 2011 Survey of Privately Funded Clinical Research Activity in Australia, 2012.

3.2 Regulatory environment and operations in Australia

Developing medical and biotechnological products for the market requires considerable investments of time and capital. The average cost of bringing a new medicine or vaccine to market is approximately USD $2.6 billion. This includes the cost of failed R&D projects. The process of primary scientific research through to clinical trials to ensure regulatory requirements are met can take between 10 to 15 years.[6]

The Australian medical and biotechnology industry also relies on international patent registration and clinical trials to operate sustainably, whilst delivering positive health outcomes to the Australian public.

In 2018, pharmaceutical companies applied for the most patents across all industry sectors in Australia. This represents 1.50% of worldwide pharmaceutical patents where Australia is ranked number 13 for global share of pharmaceutical patents [7] While this is a sizeable proportion of patents filed, it reflects the trend of industry participants filing patents based on the location of actual and expected competitor sales and manufacturing operations, rather than the patent owner's sales and manufacturing operations.

Further, the nature of clinical trials requires Australian industry participants to conduct these trials internationally to ensure efficacy of medical products provided in Australia. While the number of clinical trials in Australia grew 5% between 2017 and 2019[8], there is still significant offshore clinical trial activity for industry participants. Given Australia's small population size (and patient cohorts), Phase 3 trials (requiring thousands of patients over several years) are generally conducted offshore and can often represent a significant portion of the spend developing a product connected with a patent granted in Australia.

4. Importance of the Patent Box to the Australian medical and biotechnology industry

On 11 May 2021, the Government proposed to introduce a Patent Box regime in Australia.[9] The proposed Patent Box regime will allow medical and biotechnology companies to apply a concessional tax treatment to profits derived from eligible intellectual property rights.[10]

As currently set out in the Discussion Paper, the proposed policy design of Patent Box regime will mean that companies may be able to apply a concessional tax rate of 17% to income derived from standard patents filed in Australia after 11 May 2021.[11] The proposed policy design also seeks to align the Patent Box regime with the OECD/G20 Forum on Harmful Tax Practice (**FHTP**) framework governing intellectual property regimes, including the OECD's Base Erosion and Profit Sharing (**BEPS**) Action 5 minimum standard.[12]

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[6] As above note 2, Chapter 4.

[7] As above note 2, Chapter 5.

[8] As above note 2, Chapter 4.

[9] Allira Hudson-Gofers (Sydney) and Karen Heilbronn Lee, PhD (Sydney), Australia: New patent box in Australia: unboxedhttps://www.mondaq.com/australia/patent/1069876/new-patent-box-in-australia-unboxed.

[10] The Treasury, Patent Box Discussion paper on policy design, July 2021 <https://treasury.gov.au/sites/default/files/2021-07/c2021_177849.pdf> page 2.

[11] Above note 10, page 3.

[12] Above note 10, page 3.

BioMelbourne Network strongly recommends that Treasury also consider the context of the Australian medical and biotechnology operating environment in developing its policy design for the Patent Box regime. We believe that this is critical for the Government to achieve the policy aims for the Patent Box regime.

The policy design for the Patent Box regime needs to address the practical realities faced by the Australian medical and biotechnology industry. As discussed in section 3.2, companies in the medical and biotechnology industry have to navigate a complex regulatory environment, manage significant R&D costs and long lead-times for commercialisation, and acknowledge the need for offshoring certain types of R&D activities.

Further, as the benefits of the R&D tax incentive (**RDTI**) diminishes when a product reaches commercialisation, Australian medical and biotechnology companies may consider moving the development of highly portable intellectual property rights offshore. It is therefore imperative that the Patent Box regime would work together with the RDTI to keep investment and innovation for such intellectual property rights within Australia.

If appropriately designed, the Patent Box regime will help companies in the medical and biotechnology industry reduce its cost base in Australia, encourage investment into and expansion of local operations, and give them a competitive advantage against offshore companies.

5. Policy design

As currently proposed, BioMelbourne Network is concerned that the policy design for the Patent Box regime in Australia will not achieve Government's policy aims encouraging companies to base their medical and biotechnology R&D operations and commercialise innovation in Australia or to retain ownership of eligible patented inventions in Australia.

Generally, BioMelbourne Network recommends that the Treasury ensure that the Patent Box regime adopts simple rules in assessing eligible patents and R&D activities, identifying which profits are eligible for the concessional rate, and calculating the relief claimed.

Complex rules for the proposed Patent Box regime will require Australian medical and biotechnology companies to outlay significant compliance costs, which may result in small to medium enterprises being unable to receive the benefit of the Patent Box regime. For example, we note that the United Kingdom (**UK**) implemented a Patent Box regime in 2013. A study by the UK tax authority, the HM Revenue and Customs, found that 92% of the relief claimed under the UK Patent Box regime were for the benefit of companies with a turnover of greater than €50 million per annum.[13]

The Treasury needs to ensure that the proposed Patent Box regime is accessible and suitable for companies of all sizes, having particular regard to the fact that 86% of Australia's life sciences sector are classified as small to medium enterprises.[14] The benefit of the Patent Box regime should outweigh the costs associated with compliance in order to enable the Government to achieve its policy aims.

BioMelbourne Network's members' concerns regarding the policy design of the Patent Box relate to the following subject matters:

- tax rate;

[13] Huw James, HM Revenue & Customs, An Official Statistics Release, *Statistics on uptake of the Patent Box* (September 2020).

[14] AusBiotech, *Australia's Life Sciences Sector: Snapshot 2019* (2019).

- eligibility – patents granted in Australia;
- eligibility – patents filed after 11 May 2021;
- eligibility – definition of R&D activities; and
- eligibility – R&D activities conducted within Australia.

Each of these concerns are addressed below.

5.1 Tax Rate

The proposed concessional rate to be applied against income earned from Australian medical and biotechnology standard patents is 17% for income years from 1 July 2022. Subject to meeting the specified criteria, the Patent Box regime will reduce corporate income with a view to incentivise and support innovation in Australia.

More than 20 countries have already implemented the Organisation for Economic Cooperation and Development's (**OECD**) guidelines on Patent Boxes offering concessional tax treatments to intellectual property derived profits. However, there are marked differences in the implementation of the Patent Box regime in Australia among participating nations.

Specifically, the proposed level of the tax incentive is significantly lower than that of peer nations with similar taxation regimes and, thus, is not globally competitive in attracting foreign investment. By way of example, the UK Patent Box regime at a tax rate of 10% on all profits earned from patents. The HM Revenue and Customs survey found that the UK Patent Box regime increased investment in the UK by 10% amongst participating companies.[15]

The International Tax and Public Finance journal argued that Patent Boxes, such as the UK system, has stimulated tax competition between European nations[16] as the location of patents has become responsive to corporate income tax.[17] Accordingly, Australia must take similar steps to compete for opportunities that might otherwise go offshore.

Mohnen, Vankan, and Verspagen examined the effect of the Patent Box regime in the Netherlands in terms of the additional R&D activities that companies perform as a result of the policy.[18] They confirmed that a "bang-for buck" measure has a positive effect and can be seen as an indicator for the degree of "additionality" that occurred."[19] As it is currently proposed in Australia, the proposed concessional tax rate is uncompetitive and if not reduced could present significant challenges in retaining talent and investment which might have otherwise offset the short-term loss in tax revenue.

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[15] Huw James, HM Revenue & Customs, An Official Statistics Release, *Statistics on uptake of the Patent Box* (September 2020).

[16] Lisa Evers, Helen Miller and Christoph Spengel, International Tax and Public Finance, *Intellectual property box regimes: Effective tax rates and tax policy considerations*, vol. 22: 502-530 (2015).

[17] Rachel Griffith, Helen Miller and Martin O'Connell, Journal of Public Economics, *Ownership of intellectual property and corporate taxation*, 112(1), 12–23 (2014).

[18] Pierre Mohnen, Arthur Vankan and Bart Verspagen, Oxford Review of Economic Policy, *Evaluating the innovation box tax policy instrument in the Netherlands* (December 2016).

[19] Ibid, 2.

There is evidence to suggest that the investment "additionality" encouraged by the Patent Box regime occur on a global scale. For example, the Dutch innovation box regime[20] was found to have the potential to stimulate local economies by generating supplementary R&D activities that will provide governments with returns of scale that will ultimately outweigh the taxes forgone from introducing the measure.

We recommend that Treasury considers reducing the proposed concessional tax rate to no more than 10%, to ensure Australia remains competitive amongst peer nations. This rate will be commensurate with similar regimes offered in comparable jurisdictions, who are seeking to encourage local investment in the medical and biotechnology industry.

5.2 Eligibility

(a) Australian patent

A patent provides its registered proprietor with exclusive commercial rights to an invention, effectively preventing any third parties from manufacturing, using and/or selling the registered proprietor's inventions. As a result, a registered proprietor may consider it most commercially beneficial to file a patent based on the jurisdiction of an actual or expected competitor's manufacturing or sales operations, rather than the jurisdiction of the registered proprietor's manufacturing or sales operations.

The market in Australia for the medical and biotechnology industry is relatively small compared to the markets in the USA, Europe, China or Japan. As a result, medical and biotechnology companies often consider it more commercially beneficial to file patents in the USA, Europe, China or Japan rather than in Australia. Notwithstanding patents being filed in other jurisdictions, such patents would be held by Australian medical and biotechnology companies and most of the revenue from such patents would be taxable in Australia.

BioMelbourne Network considers the approach to limit eligible intellectual property rights to standard patents granted in Australia will likely exclude the majority of patents held by Australian medical and biotechnology companies in other jurisdictions, thereby not meeting the proposed policy objectives of the regime.

UK Patent Box regime

As an alternative, BioMelbourne Network would recommend that Treasury consider a similar approach to the UK Patent Box regime.[21] In particular, a company may be eligible to use the Patent Box regime for patents granted by:[22]

(i) the UK Intellectual Property Office;

(ii) the European Patent Office; and

(iii) selected countries within the European Economic Area,

provided that the company made a significant contribution to either:[23]

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[20] Ibid, 16.

[21] *Corporation Tax Act 2010*, Part 8A.

[22] *Corporation Tax Act 2010*, section 357BB and section 357BBA.

[23] *Corporation Tax Act 2010*, section 357BD.

(iv) the creation or development of the patent; or

(v) the creation or development of a product incorporating the patent.

It should be further noted that the UK's Patent Box regime does not only require ownership of patents in order for eligibility to arise. A company may hold an exclusive licence to a patent, provided that the company has:[24]

(i) rights to develop, exploit and defend rights in the patent;

(ii) one or more rights to the exclusion of all other persons, including the licensor; and

(iii) exclusivity throughout an entire national territory.

Ireland Knowledge Development Box

Alternatively, the Treasury may consider the Ireland Knowledge Development Box regime.[25] Specifically, a company may be eligible to use the Ireland Knowledge Development Box regime for:[26]

(i) computer programmes;

(ii) an invention protected by a patent granted by the Intellectual Property Office of Ireland or equivalent office elsewhere; or

(iii) intellectual property rights for small companies which are certified by the Controller of Patents as patentable, but not patented.

BioMelbourne Network considers the eligibility requirements under the Ireland Knowledge Development Box to be the most 'friendly' approach, and would more effectively help the Government achieve the policy aims of the Patent Box in Australia.

Appropriate mechanisms to assess patent eligibility

The Discussion Paper queries whether there is a way of judging whether the scope of claims in patents granted in other jurisdictions would be substantially similar to the scope of claims in a standard patent that would have been granted in Australia (Question 3). The World Intellectual Property Organisation considered claims granted by different offices for the 'same' invention and found that differences could be categorised in the following manner:[27]

(i) substantial differences – elements or features of the claims are different (some may be missing or others included), different categories, and different subject matter of independent claims; or

[24] *Corporation Tax Act 2010*, section 357BA.

[25] *Finance Act 2015*, section 32.

[26] As above note 25.

[27] Lutz Mailänder, Head of International Cooperation on Examination and Training Section, PCT International Cooperation Division, World Intellectual Property Organisation, *Topic 12: Utilizing Claims Granted in other Jurisdictions* (5 February 2020).

(ii) non-substantial differences – 'equivalent' scope of protection, one part claim instead of two part claims, all features are presented and only listed in order, wording is similar but uses synonymous or equivalent expressions, and additional or missing reference numerals.

Other appropriate mechanisms to determine patent eligibility could include:

(i) Global Patent Prosecution Highway[28] – a pilot program between 21 patent offices who have adopted common procedures to accelerate examination of qualifying applications;

(ii) Patent Cooperation Treaty[29] – assists applicants in seeking patent protection internationally for their inventions, allowing applicants to file one international patent application under the PCT and simultaneously seek protection in multiple jurisdictions;

(iii) IP5[30] – The IP5 is a forum of the five largest intellectual property offices in the world, comprised of the US Patent and Trademark Office, the National Intellectual Property Administration in China, the European Patent Office, the Japan Patent Office, and the Korean Intellectual Property Office. The advantage of this approach would be a narrower list of key jurisdictions from which a foreign granted patent would be recognised as an Australian equivalent; and

(iv) stricter patent regimes – Australian patent laws allow for a broader scope of patents compared to other jurisdictions. Countries with stricter patent regimens such as Europe, China, and Japan provide narrower patent protection and may be a good measure for patents that would be eligible under the Patent Box regime in Australia.

(b) Patents issued after 11 May

BioMelbourne Network notes that the time horizons and expenditure profiles necessarily incurred in the research, development, registration and exploitation of eligible patents, and associated intellectual property rights, need to be considered in the context of the medical and biotechnology industry.

Companies within the medical and biotechnology industry have to undertake extensive R&D processes and comply with strict regulatory frameworks, which means that time horizons and expenditure profiles are greatly expanded. For example, it would likely take between 5 to 10 years between the registration of a patent and when it is effectively commercialised.

Patents generally have a lifespan of up to 20 years from filing date. Taking this into account, we note that it is common for a company to make a loss for a period of 5 years after the point of commercialisation is reached before it starts turning a profit. The time limitation on the eligibility of patents means that companies would only have a very limited window to receive the benefit of the Patent Box regime.

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[28] World Intellectual Property Organisation, *PCT-Patent Prosection Highway Program* <https://www.wipo.int/pct/en/filing/pct_pph.html>.

[29] World Intellectual Property Organisation, *Patent Cooperation Treaty – The International Patent System* <https://www.wipo.int/pct/en/>.

[30] FiveIPOffices, *About IP5 Co-operation* <https://www.fiveipoffices.org/about>.

On this basis, BioMelbourne Network does not consider it appropriate that the Patent Box regime should only apply to patents issued after 11 May 2021. Instead, BioMelbourne Network recommends that all patents in existence as at the start date of the Patent Box regime, i.e. 1 July 2022, should be eligible.

We note that the UK Patent Box regime applies retrospectively to patents filed or granted prior to the effective date of the amendments to the *Corporation Tax Act 2010*.[31] This appears to be the same approach in the Patent Box regimes in Spain, France, and Luxembourg.[32]

(c) Targeting the medical and biotechnology industry

BioMelbourne Network notes that limiting the Patent Box regime to the medical and biotechnology industry is unusual. There are no other Patent Box regimes in other jurisdictions that has sought to limit eligibility to a particular industry or section. This raises a critical question for Treasury to define what would fall within the definition of 'medical and biotechnology'.

The Discussion Paper suggested the use of the IPC or CPC as a mechanism to identify medical and biotechnology patents. We consider these two systems to be too complex and leaves too much uncertainty. In particular, we note that the classification of a patent is often at the discretion of examiners in various jurisdictions, with no mechanism for applicants to challenge the classification of patents. BioMelbourne Network is concerned that the lack of a patent category defined as ‘medical and biotechnology’ could lead to the unintended consequence of patents that fulfil the form or application of a medical or biotechnology innovation being deemed ineligible.

If Treasury is of a mind to continue with this targeted approach, we recommend that the Treasury instead consider using the established definition of 'therapeutic good' under the TGA Act to provide context for what would fall within the scope of 'medical and biotechnology'.

(d) R&D conducted in Australia

The medical and biotechnology industry in Australia requires greater offshore expenditure as R&D activities progress from pre-clinical, to Phase 1 through Phase 3 clinical trials. Given Australia's small population size and patient cohorts, Phase 3 clinical trials which requires the involvement of thousands of patients over several years are generally conducted offshore. Such offshore R&D expenditure represents a significant proportion of the investment on the commercialisation of patents owned by Australian medical and biotechnology companies.

On this basis, BioMelbourne Network considers it critical that the Patent Box regime must allow a pass-through of R&D expenditure incurred offshore.

RDTI

We note that the RDTI has an established concept that a majority of R&D activities need to be performed in Australia, i.e. more than 50%, with an established approval process for assessment of eligible R&D activities. BioMelbourne Network recommends that Treasury consider applying this construct to the Patent Box regime in Australia.

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[31] *Corporation Tax Act 2010*, section 357BB and section 357BBA.

[32] Office of the Chief Economist, Australian Government, Department of Industry, Innovation and Science, *Patent Box Policies* (2015), 5.

Modified nexus approach

We understand that the OECD BEPS agenda encourages the application of the nexus approach, which requires a substantial link between the benefits derived from the commercialisation of the patent with the R&D activities contributing to those benefits.

BioMelbourne Network notes that this test is stricter than the conditions that currently apply in some Patent Box regimes. For example, under the UK Patent Box regime, a company may benefit if it is a member of a group in which another group company carried out the R&D activities provided that the company claiming the benefit played a significant role in managing the patent or product incorporating the patent.[33]

We further note that in 2015, the OECD and G20 member countries agreed on a modified nexus approach.[34] This modified nexus approach allows related party outsource expenditure, including any acquisition costs, to be taken into account provided that the proportion of income that can benefit from a Patent Box regime is the same proportion that the expenditure bears to overall expenditure (capped at 30%).[35] BioMelbourne Network recommends that Treasury consider the application of the modified nexus approach in its policy design of the Patent Box in Australia.

(e) R&D

BioMelbourne Network makes no comment on the definition of R&D proposed in the Discussion Paper, however we do wish to address the complexity around the commercialisation of patents.

Generally, it is very common for patents to be layered over time in the course of R&D activities. A product, method or process may incorporate multiple patents. We consider it more appropriate to assess eligibility under the Patent Box regime on a 'whole of product' basis, rather than on a patent-by-patent approach. Effectively, this means that once a product has an eligible patent, revenue from the entire product would be eligible for the concessional tax rate.

6. Australian tax framework

In May 2021, the Australian Taxation Office (**ATO**) reinforced its focus on implementing the OECD Transfer Pricing Guidelines (specifically, Chapters I, VI and IX) by releasing a draft Practical Compliance Guide 2021/D4: Intangibles Arrangements (**PCG**) on cross-border arrangements relating to intangibles.

Importantly, the PCG is broadly drafted to capture the use of intangible assets such as intellectual property rights through the transfer or migration of these assets between Australian entities and offshore related parties. This presents challenges for the medical and biotechnology industry in Australia with the expectation of an increased compliance burden in maintaining the required documentation and rigorous analysis of arrangements against a risk assessment framework.

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[33] *Corporation Tax Act 2010*, section 357BC.

[34] Organisation for Economic Cooperation and Development, OECD/G20 Base Erosion and Profit Shifting Project, *Action 5: Agreement on Modified Nexus Approach for IP Regimes* (2015).

[35] Organisation for Economic Cooperation and Development, OECD/G20 Base Erosion and Profit Shifting Project, *Action 5: Agreement on Modified Nexus Approach for IP Regimes* (2015), 3.

We note that whilst the PCG is not law, and does not bind taxpayers, it does give indication on how the ATO will assess and review risks associated with taxpayers. As stated above, the location of patents has become responsive to corporate income tax policy, and measures such as these undermine policies aimed at incentivising innovation and technology onshore in Australia.

We are of the view that whilst this may be beyond the scope and jurisdiction of Treasury's current deliberations, where tax compliance interferes with policy, recommendations must be made as the PCG does not align with the interests of this proposed Patent Box regime. For this reason, BioMelbourne Network recommends that Treasury considers how the ATO assessment of offshore activities in the context of intellectual property rights may better align with the incentivisation of the medical and biotechnology industry in Australia under the Patent Box regime.

Authors

Kelly Griffiths, Partner

Peter Poulos, Partner

Raisa Blanco, Senior Associate

Isabelle Smith, Associate

Ujjesha Singh, Lawyer

Eric Chen, Lawyer