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

To: Paul Fischer
Corporate and International Tax Division
The Treasury
Langton Crescent
PARKES ACT 2600

Via email: PatentBoxConsultation@treasury.gov.au

16 August 2021

From: AusBiotech Ltd
ABN 87 006 509 726
Level 3/15 Queen St
Melbourne VIC 3000
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

Introduction

AusBiotech welcomes the announcement of a patent box for Australia that will apply to the medical and biotechnology sector.

A well designed, accessible, and effective Australian patent box will support companies to keep the development of their IP and the value they create from it in Australia, to the economic and social benefit of all Australians.

As Australia's peak industry body for one of Australia's most innovative industries, AusBiotech is pleased to have the opportunity to contribute comment and recommendations on the Treasury's discussion paper *'The Australian patent box: policy design'.*

AusBiotech is a well-connected network of over 3,000 members across the medical and biotechnology industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology and agricultural biotechnology sectors.

Bridging the gap between research and development (R&D) and commercialisation is core to ensuring that Australian medical and biotechnology researchers, companies, and manufacturers remain internationally competitive by making it genuinely more viable for Australian businesses to utilise, develop and create value from Australian IP in Australia.

Despite initial reports about patent box policies being used in a manner contrary to their stated objective, the OECD/G20 Base Erosion and Profit Shifting (BEPS) Project's *Action 5: Agreement on Modified Nexus Approach for IP Regimes (OECD, 2015)* amply addresses these concerns. AusBiotech supports a design for the Australian Patent Box that is Action-5 compliant.

Analysis beyond 2015 such as that on the UK Patent Box, finds positive economic shifts and benefit from a patent box incentive, with firms using the patent box program displaying a potential 10 percent increase in investment over the incentive's post-implementation period (*Patent Box Evaluation*, HR Revenue and Customs, November 2020).

With more than 1,852 organisations and 240,000 employees, Australia has a substantial life sciences sector, which is consistently ranked as one of the top countries for biotechnology innovation globally. However, it is estimated that 86 percent of the sector is in the SME category, the majority of which is yet to reach commercialisation or earn revenue.

Therefore, the Patent Box is intended as an incentive for companies to make long-term decisions and create long term value for Australia, but most will not be eligible for some years. For example, it is well accepted that as a product reaches commercialisation, the benefits of the much-valued R&D Tax incentive (RDTI) diminish, the development of highly-portable IP may (and does) move the associated benefits offshore, where other countries benefit.

An Australian Patent Box incentive would work 'hand in glove' with the RDTI to keep more of the value creation and its benefits in Australia, for longer. This notion of 'additionality' is key to the Patent Box creating an incentive to change and improve the outcomes we might otherwise have.

That said, it is critical that the Treasury note that the companies eligible for the incentive at its start date, under the current design, will be nil, and access in the forward estimates is near impossible. It is estimated that it would take some three to five years for the first handful of companies to be eligible and up to 10 years to see any meaningful additionality created.

"…it is critical that the Treasury note that the companies eligible for the incentive at its start date, under the current design, will be nil, and access in the forward estimates is near impossible."

Summary of key recommendations

1. Australia's Patent Box should look to a tested regime in a comparable ecosystem, when considering key design elements. Notably the UK Patent Box should be seen as an exemplar for design elements such as (but not limited to) the competitive tax rate of 10 percent, transitional or introductory arrangements, a government-industry working group and eligible patents.

2. As the key consideration should be patent-ownership and point of taxation, provide eligibility to patents registered by Australian companies in jurisdictions of comparable quality for patent granting as Australia.

3. Do not use the IPC or CPC systems' classification of a patent to deem if a patent is 'medical or biotechnology', and instead look to an already-legislated definition such as the definition of a therapeutic good as shown Section 3(1) of the *Therapeutic Goods Administration Act 1989*. Instead target the definition to enable the intended recipients to access to the programme.

4. Given the Australian environment where many forms of R&D are unavailable or unworkable, apply an arrangement to acknowledge that research can and must be able to be conducted overseas, when assessing patent box claimants' substantial activity requirement.

5. Rather than assessing eligibility on a patent-by-patent basis, simplify the approach by acknowledging a 'whole of product' approach. This would mean that once a product has an eligible patent, the product would be eligible. Also, noting the time between first patent application and first revenue is when the majority of the R&D in the process occurs, the patent box design needs in to take account the common and typical circumstances of medial

and biotechnology development, where R&D may be preceded or followed by multiple patent filings of varying types on the one product or platform.

6. To ensure some companies will be eligible to access the Patent Box in the next three to five years, create a transition arrangement such as that used by the UK, or simply ensure that all eligible patents granted as at the start date of the regime (i.e. patents in existence at 1 July 2022) should be eligible patents for Patent Box purposes. Additionality would be created as there would be an incentive to keep the value creation related to the IP in Australia.

7. In eligible revenue to enter the patent box, include milestone payments, along with other forms of revenue noted (Royalties or licence fees, revenue from the sale of patented good or services or the use of patented processes, revenue from damages for infringement, revenue for sale or assignment of an invention).

Unique characteristics of the Australian medical and biotechnology sector

The Australian Patent Box is an exciting prospect for the future of our industry and could provide support for long term value creation from Australian IP, should design elements be suitable for the sector's unique characteristics.

Although welcomed, we note that the design revealed in the discussion paper does not reflect an adequate understanding of the unique characteristics typical to the medical and biotechnology sector, notably:

- The length of time between patenting and commercialisation (~10 years, see Fig.2);
- The length of time between a patent priority date and granting (issuance);
- The fact that many types of R&D cannot be conducted in Australia, due to capacity and capability limitations (for example: toxicology studies and Phase III trials); and
- The multinational patenting requirements the sector faces, given the global nature of the biotech industry, and the comparable size of international markets (of which, Australia accounts for ~1%).

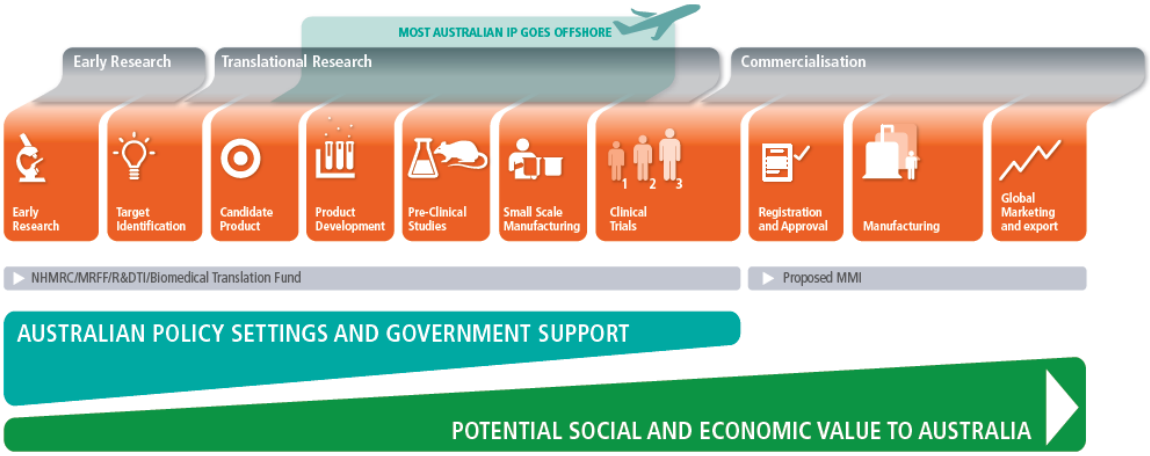

Figure 1. The typical research to commercialisation pipeline and incentives for the medical and biotechnology sector. Graphic supplied by CSL Limited.

Patent box design considerations

Key issue/s: One critical reason Australia needs a patent box incentive, is to be competitive with comparable medical and biotechnology ecosystems. The proposed concessional patent box rate of 17 percent is not competitive and, when compliance costs are considered, provides little financial incentive. The restrictive nature of the proposed regime would be an additional burden to the existing high costs and barriers for commercialising medical and biotechnology innovations in Australia. Additionally, with the current tax rate for companies at 25 – 30 percent, 17 percent does not constitute a significant incentive. Reasoning that supports this proposed rate may suggest that the global minimum tax rate will be set at 15 percent sometime in the future, is speculative and premature.

The United Kingdom's (UK) Patent Box has long been coveted from an Australian perspective. While it is not a perfect fit, it has already worked through solutions to so many technical elements of the regime.

Australia does not need to start from the beginning, but instead can adopt key elements of the UK's regime, which has "micro-level analysis suggests a potential 10 percent increase in investment by firms that use the patent box" and is fully BEPS and OECD-compliant. (*Patent Box Evaluation*, HR Revenue and Customs, November 2020).

Recommendation: Australia's Patent Box should look to a tested regime in a comparable ecosystem, when considering key design elements. Notably the UK Patent Box should be seen as an exemplar for design elements such as (but not limited to) the competitive tax rate of 10 percent, introductory arrangements, government-industry working group and eligible patents.

In Response to:
Q1. *What features of patent boxes in other jurisdictions are most significant and important for designing the Australian patent box to support the medical and biotechnology sectors?*

The Australian patent box should look to the UK patent box regime's key elements and implementation provisions as a template, specifically:

a) Introduce the concessional tax rate at 10 percent to ensure Australia is competitive with comparable medical and biotechnology ecosystems.

b) A company elects to be in the patent box regime. Once elected to be in the regime all eligible patents already granted to the company at that point in time are included.

c) Allow for a further election that would allow a company to include profits from patents that were on application at the time the company first made the election into the regime. This additional election is made in the year the patent is eventually granted and allows a company to then include any profits that were made in the period between application and grant of the patent.

This is done on a case-by-case basis to allow a company to include any pre-grant profits into the regime (whilst also avoiding any pre-grant losses). There are time limits for including any of these pre-grant profits. Once the patent is granted, it is automatically in the regime regardless of whether it is loss or profit making.

d) The establishment of a Government-Industry working group or task force to assist the Government's development of the design and implementation of the Australian patent box. Ther UK established a working group of representatives from industry to complement wider consultation on the Patent Box and to discuss options and proposals in more detail (https://www.gov.uk/government/consultations/the-patent-box). For Australia, this group might include skilled corporate taxation life sciences experts as well as industry and policy experts, such as:
    - Relevant industry organisations' CEOs, including AusBiotech, MTAA and Medicines Australia;
    - Taxation experts that specialise in life sciences;
    - CEOs and tax experts from multinational companies and Australian SMEs working in medical and biotechnology.

Eligible IP to enter the patent box

Key issues: As currently proposed, IP eligible for the patent box incentive must be registered with IP Australia as an Australian standard patent.

This parameter fails to understand patent strategies employed by the Australian medical and biotechnology sector, whereby patents are generally filed at patent offices within target markets - the location of actual and expected competitor sales and competitor manufacturing, as opposed to filing the patent in the owner's own home country.

Limiting a Patent Box to Australian patents only would immediately exclude a likely majority of Australian-owned IP.

Recommendation: As the key consideration should be patent-ownership and point of taxation, provide eligibility to patents registered by Australian companies in jurisdictions of comparable quality for patent granting as Australia.

In response to:
Q2: Are patents applied for by medical and biotechnology companies with domestic R&D operations generally Australian standard patents? and

Q3: In instances where an invention is patented in other jurisdictions but not in Australia, is there a way of judging whether the scope of claims in these patents would be substantially similar to the scope of claims in a standard patent that would have been granted in Australia?

Strategies employed by most Australian medical and biotechnology companies with domestic R&D operations, generally hold patents issued overseas in target markets. In these instances, patents issued in comparable jurisdictions should be deemed eligible.

Appropriate mechanisms to deem patient eligibility include:

a) The Global Patent Prosecution Highway (GPPH), a pilot program between 21 patent offices who have adopted common procedures to accelerate examination of qualifying applications.

b) The Patent Cooperation Treaty (PCT), which assists applicants in seeking patent protection internationally for their inventions. By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a large number of countries.

c) Patents issued by the IP5. 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.

   Australian patent laws allow for broad scope of patents compared to many countries. Therefore, countries with stricter patent regimens, such as Europe, China, and Japan (all members of that IP5) often provide narrower patent protection and would therefore be a good proxy for patents that would be allowable in Australia.

Targeting medical and biotechnology

Key Issues: No patent box in the world has sought to limit its application to a particular industry or sector, and therefore there are no precedents or international examples for Australia to look to when defining 'medical and biotechnology'.

The discussion paper suggests the use of the IPC – *International Patent Classification* system as a mechanism to identify medical and biotechnology patents. The IPC, however, is too complex and granular for the specific task of determining what may be medical and biotechnology. With no definitions provided, the multi-class IPC system classifies patents into sections, class, subclass, group, main group, and subgroup, with no clear section or subsection at any levels of classification reserved for 'medical and biotechnology' patents.

The CPC - *Cooperative Patent Classification* is an extension of the IPC but only further adds to the complexity. This system would also be inappropriate for determining medical and biotechnology IP.

It would be unclear, under either classification system, which patents would be deemed 'medical and biotechnology patents' as there is no matching category/ies. See below (Figure 2, which shows the various levels of the classification system, to give a 'flavour' of the complexity that this option proposes.

Further, the classification of a patent is in effect, at the whim of examiners in the patent office. With no mechanism for applicants to challenge the classification of the patent, the lack of a patent category defined as 'medical and biotechnology' will lead to the unintended consequence of patents

that fulfill the *form* or *application* of a medical or biotechnology but do not meet the 'correct' classification being deemed ineligible.

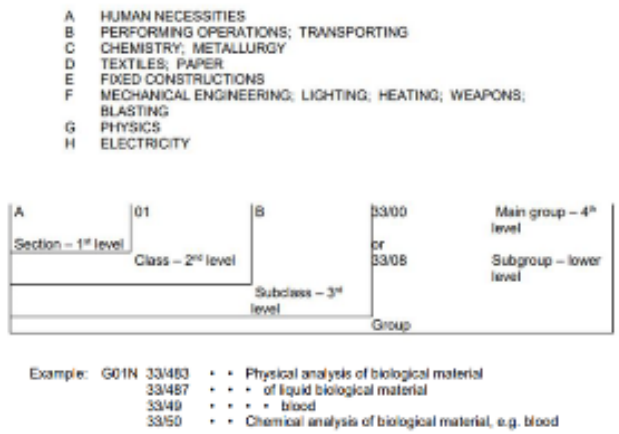

Figure 2. Schematic representation of the International Patent Classification System and the multiple layers of complexity.

Recommendation: Do not use the IPC or CPC systems' classification of a patent to deem if a patent is 'medical or biotechnology', and instead look to an already-legislated definition such as the definition of a therapeutic good as shown Section 3(1) of the *Therapeutic Goods Administration Act 1989*. Instead target the definition to enable the intended recipients to access to the programme.

In response to:
Q4: What is the best approach to provide certainty around access to the regime for the medical and biotechnology sectors? and

Q5: What are the core concepts/applications that need to be covered by any definition of the medical and biotechnology sectors for the purpose of defining access to the patent box?

The best approach to provide certainty of access, and define the scope of 'medical and biotechnology' would be to use the definition of 'therapeutic good' and 'therapeutic use' as stated in Section 3(1) of the *Therapeutic Goods Administration Act 1989*:

"therapeutic use means use in or in connection with:

> *(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or (b) influencing, inhibiting or modifying a physiological process in persons; or (c) testing the susceptibility of persons to a disease or ailment; or (d) influencing, controlling or preventing conception in persons; or (e) testing for pregnancy in persons; or (f) the replacement or modification of parts of the anatomy in persons.*

therapeutic goods means goods:

> *(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:*

(i) for therapeutic use; or (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);"

In either case, more clarity is required from the Treasury on the intended recipients of the Patent Box.

Applying the substantial activity requirement

Key issue: Given domestic limitations in capacity and capability, the development of Australian medical and biotechnology requires offshore pre-clinical and clinical trials research. Some R&D, such as toxicology studies, are often unavailable domestically.

Additionally, due to Australia's small population size, and therefore a lack of patient cohorts that meet critical mass, Phase III clinical trials that require thousands of patients over several years, generally need to be conducted offshore and can often represent a significant portion. If eligible R&D is limited solely to the proportion of associated R&D that was conducted in Australia by the company, it will severely diminish access to the patent box, through no fault of the company.

Recommendation: Given the Australian environment where many forms of R&D are absent or unworkable, apply an arrangement that will allow for research to be conducted overseas, when assessing patent box claimants' substantial activity requirement.

In Response to:
Q12: How much R&D activity (related to patented inventions) occurs outside Australia? How is R&D usually split between related and unrelated parties?

As research often occurs outside of Australia in relation to patented inventions, for reasons of necessity. For example, we know that many companies avail themselves of 'overseas findings' under the RDTI scheme

Preclinical toxicology studies, and phase III clinical trials are the most common examples of R&D that in many cases cannot be undertaken domestically.

Definition of R&D

Key issue/s: While we make no comment on the definition of R&D proposed, this section of the discussion paper asks about *the role of R&D that occurs after a patent has been applied for.* This period is typically up to 10 years and is characterised often by multiple patents applications over the transitional period. Patent protection is usually sought very early in the development cycle, and it is common for patents to be layered over time on a base or platform technology, as new milestones are reached and new IP discovered, new patents can be applied to the same technology for different reasons.

It is also common for the time between first patent filing and commercialisation to be around seven to 10 years, sometime longer. One invention can have a number of patents, such as the methods of manufacturing, generally referred to as utility patents or, in some cases, design patents, which are typical in biologicals and medical devices.

Patents are used to protect the invention of a product, method, or a process.

Using medicines as an example, patents could be filed in key market jurisdictions throughout the development process. Often during the early discovery phase patents will be filed around the molecule or compound. Later in preclinical/clinical phases, the method of treatment, routes of administration and clinical dosage patents may be filed.

R&D may, and does occur before and after various, patentable milestones and discoveries along the path to commercialisation.

Recommendation: Rather than assessing eligibility on a patent-by-patent basis, simplify the approach by acknowledging a 'whole of invention' approach. This would mean that once a product or platform has an eligible patent, revenue from the entire invention would be eligible for the concessional tax rate. Also, noting that the time between first patent application and first revenue is when the majority of the R&D in the process occurs, the patent box design needs to take into account the common and typical circumstances of medical and biotechnology development, where R&D may be preceded or followed by multiple patent filings of varying types on the one invention, product or platform.

Q16: How significant is the role of R&D that occurs after a patent has been applied for? What portion of an invention's total R&D would this typically account for in the medical and biotechnology sectors?

No collected data is currently available on this, however, industry experience suggests 80 percent or more of the R&D would occur after the first patent application on a platform or product. Typically, some form patent protection would be present when an invention is at a pre-clinal stage and the phase 1 - III clinical trials would subsequently occur, a process that may and often does last up to 10 years. Early IP protection is important in biotechnology development as it enables the developers to attract private capital, often in the tens-of-millions of dollars to progress through clinical trials.

Case study example: *A Victorian-based biotechnology company with a late-stage clinical oncology asset in development, globally patented their invention over 10 years ago, prior to which less than 5 percent of the R&D had taken place.*
Subsequent to the initial patent filing, approximately 95 percent of R&D expenditure has taken place on preclinical regulatory studies, manufacturing scale-up and analytical development, and clinical studies, with almost 70 percent of expenditure on clinical studies. Further, since the additional patent filing, an additional six patent families have been filed on related aspects of the initial invention.

Q17: To what extent are Australian-based manufacturing processes subject to their own patents in the medical and biotechnology industry?

No data is available on this however, anecdotally we know it is significant. 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 and looking instead to 'data exclusivity'.

Our industry is critically aware of new technologies in the global pipeline, in particular cell and gene therapies – or regenerative medicines – and the development of mRNA for vaccine development and other applications. All of these will be reliant on IP protection on manufacturing processes.

Implementation and start date

Key Issue/s: A patent box that only recognises patents with a priority date after 11 May 2021 as eligible for the incentive will be inaccessible to most companies for the better part of the next decade. This parameter fails to understand the time horizons, related expenses, waiting times and pathways for patent filing and granting that have been discussed throughout this submission.

It is usually many years from the initial patent application filing date until the patent is granted.

Under the current policy design, this five to 10-year process would prohibit potential claimants from accessing the patent box over the coming decade.

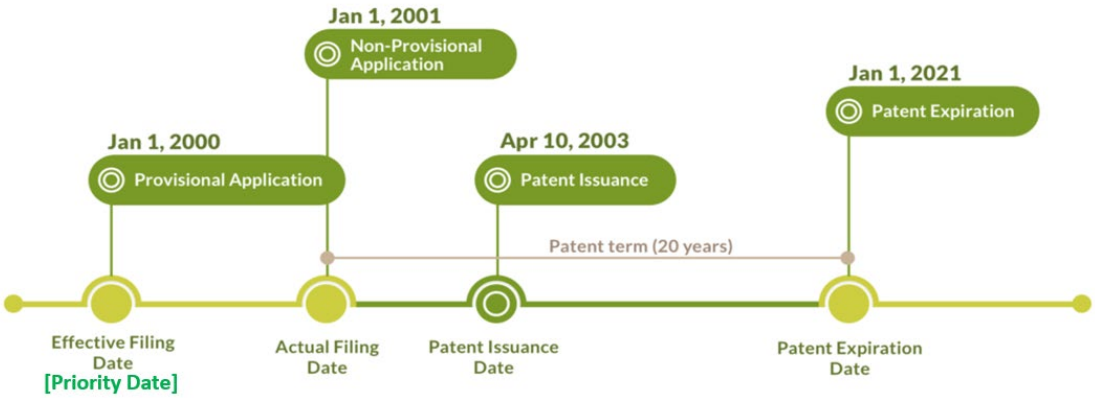

Figure 3. The general lifecycle of a patent in the medial and biotechnology sector. The time lapse between effective filing date and patent issuance can be 3 - 5 years. The provisional Application date is also called a priority date.

Recommendation: To ensure some companies will be eligible to access the Patent Box in the next three to five years, create a transitional arrangement such as that used by the UK, or simply ensure that all eligible patents granted as at the start date of the regime (i.e. patents in existence at 1 July 2022) should be eligible patents for Patent Box purposes. Additionality would be created as there would be an incentive to keep the value creation related to the IP in Australia.

In response to:
Q18: What will be the implications of targeting the patent box to new patented innovations (i.e. have a patent priority date after 11 May 2021)? and

Q19: Would a start date for the patent box's concessional tax treatment of income years commencing on or after 1 July 2022 give companies enough time to prepare for the regime? How would it impact on new R&D?

The consequence of targeting the patent box only to new patented innovations (i.e. patent with a priority date after 11 May 2021 would see few, if any Australian companies able to access the patent box from 01 July 2022.

Consideration should be given to the UK's approach to implementing a patent box regime, where a company must elect to go into the regime in order to benefit. This election is made at the company level and once made, would cover all eligible patents, regardless of whether granted pre- or post-commencement of the regime.

For any patents not yet granted, provided a company has elected to go into the regime it may make a further election (on a patent-by-patent basis) to enable profits to benefit from the Patent Box that arise in the period from application to the date the eligible patent is granted. This look-back period may be limited to the later of the start date of the regime (i.e. 1 July 2022), the date the patent application is filed, the date the company elected into the regime or six years before the right is granted.

Eligible revenue to enter the patent box

Key issue/s:
The discussion paper notes that "value derived from IP comes in many forms" and AusBiotech agrees that the forms noted as most commonly associated with the commercialisation of patented inventions should be eligible. However, we also note that milestone payments are a common occurrence in this sector and have not been considered for inclusion.

Recommendation: Include milestone payments, along with other forms of revenue noted (Royalties or licence fees, revenue from the sale of patented good or services or the use of patented processes, revenue from damages for infringement, revenue for sale or assignment of an invention) in the revenue eligible to enter the patent box.

In response to:
Q20. What types of patent-related revenue should be eligible for the patent box?

A key omission from the eligible revenue that is specific and common for this sector is the inclusion of upfront partner payments and milestone payments in eligible revenue. In practice, due to the typical development requirements, Australian medical and biotechnology companies often partner with large multinational pharmaceutical groups to undertake R&D, as well as to access funding and expertise. The patent box design should include such milestone payments in eligible revenue.