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CONSULTATION ON PATENT BOX POLICY DESIGN

Response to Treasury

by

Medical Technology Association of Australia

Submitted

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1. 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?

RESPONSE to 1.

Background

MTAA supports the patent box policy providing that its design will provide an incentive for the commercialisation and manufacturing of medical technology in Australia. That is, the policy will augment and harmonise support beyond research and development – by incentivising the retention in Australia of the whole-of-life cycle processes of commercialisation, manufacture, growth and export.

The global COVID-19 pandemic has cast a spotlight on the importance to Australia of supporting local innovations and their pathway to global commercialisation. Prior to COVID-19, Australia had experienced erosion in medical manufacturing because it was not an internationally competitive location to commercialise medical products / pharmaceuticals. For example, Pfizer's closure of its Bentley, WA facility, to be completed by 2024, will result in the loss of 470 facility jobs and those in its supply chain, and loss of exports to North America, Europe, China and Latin America. This situation is occurring in an overall environment in which Australia would benefit significantly from the creation of a skilled workforce, export opportunities and increasing medical supply sovereignty, which are now government priorities (e.g., Modern Manufacturing Strategy).

In light of this, MTAA proposes the formation of a permanent working group (PWG) to support Treasury's objectives and processes to implement the patent box. The PWG, consisting of medical technology and biotechnology experts, local manufacturers (including SMEs) and supply chain experts, and tax experts in the life-sciences field, will engage with Treasury and other groups, as the process progresses and provide insights to ensure that the intended beneficiaries of the policy will find the policy instrumental to stimulating innovation. MTAA understands that Treasury has planned future consultations, however, we believe that the medical technology industry's position is most effectively served via a permanent working group – considering that this is the first time that government has offered a corporate tax incentive to specific sectors to facilitate growth.

Examples of member organisations to include in the PWG are: MTAA, Research Australia, Medicines Australia, AusBiotech, Department of Industry, Science, Energy and Resources, Export Council of Australia, representatives from the Supply Chain Initiative and the Modern Manufacturing Initiative.

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As Treasury is aware, other jurisdictions have used patent box incentives to mitigate any relative disadvantage to high-value investments in medical manufacturing by reducing corporate tax rates on revenues earned from the sale of intellectual property.

Countries that have such incentives are:
United Kingdom, France, Switzerland, Singapore, Israel, Ireland, India, China, Andorra, Belgium, Cyprus, Greece, Hungary, Italy, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Slovakia, Spain, Turkey, South Korea and Vietnam. Features of legislation in those jurisdictions are instructive for the implementation of the patent box in Australia.

Features
Lower tax rate: UK 10%, Ireland 6.25%, Belgium 6.8%, Luxembourg 5.84%, Netherlands 5%, China 15%. The proposed rate of 17% is not sufficiently competitive. MTAA recommends an effective rate of 10%. Data source: Atkinson & Andes, PWC 2013:13.

Other jurisdictions have learned that initially, their patent box legislation design had the unintended consequence of transferring IP for the purpose of accessing the benefit, rather than stimulating manufacturing. Changes have been made to mitigate this, in countries such as the UK. MTAA would welcome legislative design that reinforces the benefits to Australia: beneficial IP ownership, a tax base, R&D and manufacturing here in Australia.

Effective date: The patent box applies to intellectual property based on patents lodged with IP Australia after 7.30pm, 11 May 2021. The policy should consider extending this date backwards three years, to include patent applications that were lodged prior to 11 May 2021, but not yet granted or developed.

In Australia, patent applications are typically lodged years before they become commercially viable. The selection of a date this year effectively defers any real benefit five to ten years hence, as this is the development time required to get products to the commercialisation and manufacturing stages. The selected date means that innovation that is being commercialised now (with IP filing dates prior to 11 May 2021), cannot ever access this tax concession. Thus, Australia's competitive disadvantage would continue in future years, due to the time lag.

Definition: Other criteria should be considered for determining eligibility, other than jurisdiction of IP holding (IP Australia patent status), such as location of manufacturing plant, supply chain support, where the IP is beneficially held. For determining whether a product is a medical device, IP patent status provides little clarity. For medical devices, consideration can be given as to whether or not the product is registered as a therapeutic good. However, this should not be a necessary condition because it could result in unintended consequences – increases in TGA Class 1 applications at a time when the TGA has revised its Class 1 application process, making approval The TGA has revised its Class 1 application process, it is no longer automatically granted. Further consideration of how therapeutic good classifications may assist or impede the patent box process is required.

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Medical devices typically have several / many components, each with patents that were applied for at different times and held by different countries / companies. Where only some of the product has an Australian-held patent, the relative contribution to revenue is difficult to assess.

For example, there are differences between situations where there is a patent for a new product, a patent for a new therapeutic use of a product that has already been commercialised or a patent that claims a method for manufacturing a product (and not the product itself). How will the relative contribution of the new patent, new therapeutic use or new method of manufacture be assessed? Answers and solutions can be developed within the PWG so that all stakeholders have opportunity to mitigate unintended consequences.

2. Are patents applied for by medical and biotechnology companies with domestic R&D operations generally Australian standard patents?

3. 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?

RESPONSE - YES – to both 2 and 3.

The information that MTAA has at the present time is that while IP Australia patents are applied for, they are not necessarily essential for Australian manufacturers to beneficially own the IP out of Australia, so this can't be the main criteria to assess this. The IP Australia patent application process takes longer than patent applications in China, the USA and Europe. Given that Australia is a considerably smaller market for the commercialisation of medical technology – global markets provide greater opportunity for growth, therefore, patents in Europe, UK, USA and China are prioritised.

Medical knowledge and innovation grows at a rapid rate, science and patent information is in the public domain and globally shared, the evaluation processes that IP Australia conducts have elements in common with processes in other jurisdictions – the assessments are based on the same research. However, holding the patent with IP Australia should not be the sole test for eligibility.

4. What is the best approach to provide certainty around access to the regime for the medical and biotechnology sectors?

5. 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?

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RESPONSE to 4 and 5.

The formation of a PWG is considered the best approach to achieve certainty and address the core concepts as follows:

- IP Australia patents definitions;
- Consideration of regulatory listings and approvals;
- Location of manufacturing facility with a nexus to R&D, to ensure that it does not become a mechanism by which IP is transferred to access the benefit without stimulating manufacturing in Australia.;
- Scope of the business – commercialisation and manufacturing processes are in place in Australia, versus distribution processes;
- Develop key indicators to ensure the intended product revenue is the actual revenue subject to the lower tax rate;
- Definitions of commercialisation, manufacture and export – R&D is not separate from commercialisation. Both are activities that occur synergistically in order for an innovation to have a commercially successful outcome;
- An explanation about the exclusion from the policy, of manufacturing income – the intention of the exclusion is unclear and seems counterintuitive to the purpose of the patent box. What is the purpose of separating of 'manufacturing' income from 'IP-derived income'? The incentive is for manufacturing to be established and sustained here, not license the IP for manufacture elsewhere;
- Qualifying income - to include royalties, license fees, sale of qualifying IP, sales of patented items (product sales), IP derived income (e.g. from patented services) and infringement income;
- R&D definition would be linked to the definition in RDTI legislation (qualifying expenditure to include overseas clinical trial expenses).

6. What sort of businesses own patented inventions relating to low emissions technologies, and would introducing a tax concession through a patent box support the clean technology energy sector?

RESPONSE to 6.

MTAA does not have a position on this at the present time.

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7. Do patents play a strong commercial role in the clean technology energy sector, or are other strategies for using IP more important (such as being first to market)?

8. What factors drive decisions about the location of clean technology R&D?

9. How would the clean technology sector best be defined for the purposes of a patent box?

10. Would a patent box be an effective way of supporting the clean technology sector? Are there other options available to encourage growth in this sector?

RESPONSE to 7 through 10.

MTAA does not have a position on this at the present time.

11. Do existing record keeping systems allow companies to show how R&D expenses are related to patented inventions? Can companies divide this into expenses incurred in Australia and elsewhere in order to calculate the proportion of R&D related to the patented invention that occurred in Australia?

12. How much R&D activity (related to patented inventions) occurs outside Australia? How is R&D usually split between related and unrelated parties?

RESPONSE to 11 and 12:

MTAA needs to undertake further consultation on this question and bring findings back to the PWG. The ATO has criteria for establishing beneficial ownership. A minimum nexus could be set, rather than attempting to apportion expenses / efforts relative to IP, to determine where the IP is beneficially owned and where sustained economic benefits are occurring, i.e., jobs, supply chain, growth in Australia.

13. Is the existing legal framework for the R&D tax incentive appropriate for determining R&D conducted in Australia for the purposes of the patent box? Do companies already collect this type of data and report it to the Government in some way (such as for the R&DTI)?

14. To what extent are the R&D expenses of Australian patented inventions not entirely the subject of R&DTI claims?

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15. Could any existing definitions of qualifying expenditure (such as in the UK) in relation to the development of patented inventions be adopted in the Australian context?

16. 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?

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

RESPONSE to 13 through 17.

MTAA needs to undertake further consultation on this question and bring findings back to the proposed PWG. The majority of R&D expenditure occurs after the patent application has been lodged because that is when further research / trials are done. Patent applications provide certainty that building investments and further commitments to the technology.

Specifically, in relation to #17, there is not sufficient manufacturing here, relative to our potential. Process supporting IP is fundamental to ensuring the sustainable manufacturing can economically thrive.

18. 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)?

19. 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?

RESPONSE to 18 and 19.

Patent applications lodged prior to this date but not granted will be excluded. Companies in this situation are already disadvantaged, relative to their competitors (who lodged after this date) as they are commercialising and manufacturing over the same time frame. For example, the announcement of the patent box policy has not deterred a member company from moving commercialisation and manufacturing off-shore (to Ireland) because their patents don't qualify, even though business and job growth could continue in Queensland. As mentioned above, the benefits of the patent box will not be realised for many years, due to the long lead time from patent filing to R&D / commercialisation / manufacturing, up to ten years.

20. What types of patent-related revenue should be eligible for the patent box?

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21. How far downstream can the patent box's concessional treatment apply, and what principle should be used to define eligible income derived from the patented innovation?

RESPONSE to 20 and 21.

- IP Australia patents - eligible IP to include patents, agreed non-patent IP regulatory protection, and copyrighted software.
- Margins on products manufactured here in Australia
- IP holding conditions to include full ownership or exclusive license.
- IP held elsewhere where innovation in production or design or manufacture is demonstrated to be occurring in Australia, providing the IP assets and residual cash flows are clearly held in Australia.

22. In circumstances where a single product comprises of a group of related patented innovations, what approach could the patent box use to simplify the calculation of eligible revenue and the R&D fraction?

23. As non-patent revenue will need to be separated from the eligible revenue, how might this be achieved optimally (having regard to existing systems and record keeping)?

RESPONSE to 22 and 23.

The formation of a permanent working group would provide for research on this topic in consultation with tax experts in the life-sciences.

If the IP is beneficially owned in Australia, with a nexus to significant R&D and manufacturing here, then the benefit should apply. i.e., the product meets the criteria or it doesn't, rather than attempting to proportionally attribute to IP. Virtually all revenues for medical- and bio-technologies are derived from patented IP. Value can be attained synergistically from a product, from two or more patents, without the possibility of reliably separating out the specific contribution of any one particular patent.

24. Having regard to existing systems and record keeping how might eligible expenses be optimally separated from non-eligible expenses?

RESPONSE to 24.

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The formation of a permanent working group would provide for research on this topic in consultation with tax experts in the life-sciences.

25. How should losses associated with either the development of a patented invention or its commercialisation be treated, both within the patent box and for general corporate tax purposes?

RESPONSE to 25.

The formation of a permanent working group would provide for research on this topic in consultation with tax experts in the life-sciences. In general, the losses should be subject to the same rate as the income.

26. What is the likely regulatory burden in relation to administrative, record keeping or evidentiary requirements required to access the patent box concession?

27. Are there design features of any existing patent boxes that, if adopted in Australia, would minimise the regulatory burden on companies?

RESPONSE to 26 and 27.

The formation of a permanent working group would provide for research on this topic in consultation with regulatory experts and IP Australia.

28. The ATO will administer the patent box via taxpayer self-assessments within the corporate tax system. What types of evidence would taxpayers be able to provide that would support claims that patented inventions relate to eligible sectors?

RESPONSE to 28.

The formation of a permanent working group would provide for research on this topic in consultation with tax experts in the life-sciences.

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29. Are there any other issues you would like to raise for consideration in the design of the patent box?

RESPONSE to 29.

No, thank you for the opportunity to respond to the consultation. MTAA welcomes sustained engagement with Treasury on the patent box policy design.

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