Patent Box
Discussion paper on policy design

Cochlear Submission
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Summary

Cochlear congratulates the Government for introducing a patent box regime for the medtech and biotech industries in Australia. With the right design, Austalia's patent box will be an important building block in keeping our world leading medical and biotech companies in Australia. It will also make investment in newer companies more attractive, enabling the development of new, globally competitive Australian medtech and biotech companies. Ultimately, incentivising medtech and biotech companies of all sizes to keep their intellectual property ownership and manufacturing in Australia will create economic benefits for all Australians through well paid jobs, tax revenues and capital investment.

The design and management of the Australian scheme will be critical to ensuring it helps create these economic benefits for Australia and delivers on the stated policy objectives of government – encouraging companies to base their medical and biotechnology R&D operations, and commercialise innovation, in Australia; and retaining ownership of eligible patented inventions in Australia.

To achieve these objectives the Australian patent box must:

- be competitive with similar incentives offered in peer nations;
- strike an appropriate balance between administrative integrity and being workable and practical for those using the regime; and
- reflect and accommodate the nature of the sector that it is seeking to target and attract.

Some of the broad design features of the scheme as proposed in the Discussion Paper – and that appear to be locked in – would fundamentally compromise the workability and effectiveness of the scheme in achieving its policy objectives. These are:

- *An effective concessional tax rate of 17 per cent*– this is significantly higher than the rate offered by peer nations and would not be globally competitive in attracting new investment. The rate should be lowered to 10%.

- *Only inventions claimed in standard patents granted by IP Australia* – ownership of the patent and the location of the R&D should be the focus of the scheme not where a patent is filed. Most medtech and biotech companies file patents based on competitor sales and manufacturing not where the R&D or invention occurred. Eligible patents for the Australian patent box should include patents granted to Australian companies in jurisdictions of comparable quality in a manner consistent with the rules and regulations of IP Australia governing standard patents.

- *Only patents applied for after the Budget announcement* – given the long development timeframes for intellectual property in the medtech/biotech sectors, it can easily be between 5-10 years from when a patent is applied for and when it generates revenue. The proposed approach would likely lock most of the sector out of the patent box for several years. Most (if not all) of the global IP regimes do not apply this kind of restriction, in contrast they enable all existing patents to qualify. The Australian regime should take the same approach or, at a minimum, apply to patents that are in products first commercialised after the announcement date (i.e., products that earn their first revenue after the date)

We urge the Government to change these proposed design features to make sure the patent box is as successful as possible. We also believe the current UK patent box (now OECD BEPS compliant) provides a strong framework for the Australian model, subject to some adaptation to ensure it fits our broader regulatory and legislative environment including leveraging our R&D Tax Incentive.

Further information and responses to questions are detailed in our submission.

About Cochlear Limited

Cochlear is the global leader in implantable hearing solutions. We commenced operations in 1981 as part of the Nucleus group and in 1995 listed on the Australian Securities Exchange (ASX). Today, Cochlear is a Top 50 ASX-listed company with annual global revenues of $1.4 billion. Cochlear has a significant international footprint selling in over 180 countries and a global workforce of more than 4,000 people. Since 1981, Cochlear has provided more than 650,000 implantable devices, helping people of all ages around the world to hear.

While globally successful, Cochlear is also proudly Australian. With our global headquarters at Macquarie University (MQU) in Sydney and manufacturing facilities at MQU, Lane Cove and Brisbane, we currently undertake more than two thirds of our research & development (R&D), manufacture more than 85% of our products, and employ more than 1700 people in Australia.

In FY19/20 Cochlear invested more than half a billion dollars in Australia including more than $228m in wages, $150m in payments to suppliers (with $84million to small businesses) and around $110m on R&D. Cochlear generates more than 95% of its revenue offshore but paid 70% of its global corporate tax ($77m) in Australia in FY20.

Australia has been Cochlear's R&D and manufacturing engine room for 40 years. We have significant capital and intellectual infrastructure here as well as deep commercial and research relationships with numerous universities, suppliers, and other organisations. However, Cochlear's most recent major investments in expanding capacity have been overseas – Kuala Lumpur, Malaysia and Chengdu, China. As Cochlear's business and global footprint continues to grow we have greater flexibility in where we conduct R&D whether alongside current R&D capacity in Belgium, Sweden or the United States or co-located with new manufacturing facilities in Malaysia and China.

These countries, and many others, actively and aggressively compete for our R&D and manufacturing investment by offering a suite of investment incentives including, in more than 20 other countries, patent boxes. Cochlear's preference is to invest in Australia to the greatest extent possible where it makes sense for the future of our business and provides value to our customers, employees, and shareholders. The design of the new Australian patent box will be an important factor in making these decisions.

Response to Questions in Discussion Paper

Patent box design considerations

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?

The patent box must reflect that for the Australian medtech and biotech sectors to be successful they need to succeed in global markets. It also needs to recognise and reflect that it is difficult, if not impossible, for medtech and biotech companies to access all the necessary R&D skills and expertise, and patient populations for clinical research, they need to successfully commercialise products from within Australia. Finally, the patent box should reflect the time horizon(s) and expenditure profiles incurred in the development, granting and exploitation of eligible patents in these sectors. Consequently, the patent box should:

- Broadly encompass patents filed internationally but owned/taxed in Australia and developed from Australian R&D.
- Be offered to patents granted by the commencement of the regime (1 July 2022) or, at a minimum, that are in products commercialised (meaning generate first revenue or have their first sales) after 11 May 2021
- Qualifying income should include all profits from sales of products that incorporate the patent, plus royalties and gains on sales of patent rights.
- Offer a 10% tax rate consistent with competing regimes
- Allow third-party and related party pass-through third-party R&D expenditure

- Allow acquired IP to be considered eligible. Many global regimes permit acquired IP to be eligible with only the additional eligible R&D conducted by the 'new' owner included in the nexus ratio calculation.

Eligible IP to enter the patent box

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

A patent provides its owner with a right to prevent third parties from making and selling the owner's inventions. As a result, where patents are filed is mostly based on the location of actual and expected competitor sales and manufacturing, rather than the patent owner's sales and manufacturing. More specifically, the Australian market is much smaller than the North American, European, and Asian markets. Medtech and biotech companies have more sales to gain from competitors with patents in those markets. This means it is more advantageous to file patents in those markets than Australia. As less than 5% of Cochlear's revenue is generated from Australian sales, protecting our competitive position in Australia is much less relevant than protecting it in our largest revenue generating markets.

This is why although Cochlear undertakes at least 70% of its global R&D in Australia, most of our patents are filed internationally. As of 30 June 2021, Cochlear's portfolio of active patent totals more than 1,600 patents and patent applications with most assets in the USA, Europe, and China. These patents are Australian owned, and revenue generated from the products incorporating these patents are taxed in Australia. The filing of patents in a different country does not change this.

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?

The scheme should provide eligibility to patents granted to Australian companies in jurisdictions of comparable quality for patent granting. There are a couple of options for this including requiring companies to certify that the patent has been subject to a substantive examination of comparable quality to that of IP Australia.

Targeting medical and biotechnology

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?

At a high level we believe the best approach will be focused on encouraging the medtech and biotech sectors to use the patent box rather than focusing on potential loopholes that could be exploited by those outside of the sector. This would apply whether a patent level test or income streaming test was applied.

No other patent box regime has sought to limit its application to a particular industry or sector. As a result, there are no precedents or international examples for Australia to look to when defining medical and biotechnology sectors in this context.

The discussion paper suggests the use of the International Patent Classification (IPC) system as a mechanism to identify eligible IP. The IPC, however, is too complex and granular for the task, with no definitions provided, the multi-class system classifies patents into sections, class, subclass, group, main group and then subgroup, with no clear section or subsection for 'medical and biotechnology' patents. The Cooperative Patent Classification is an extension of the IPC but only further adds to the complexity.

An alternative option is to use the legislated definition of 'therapeutic good' and 'therapeutic use' under the section 3(1) of the *Therapeutic Goods Act 1989* (Cth) and associated regulations. Therapeutic goods include medicines, medical devices, and other goods such as blood products and disinfectants.

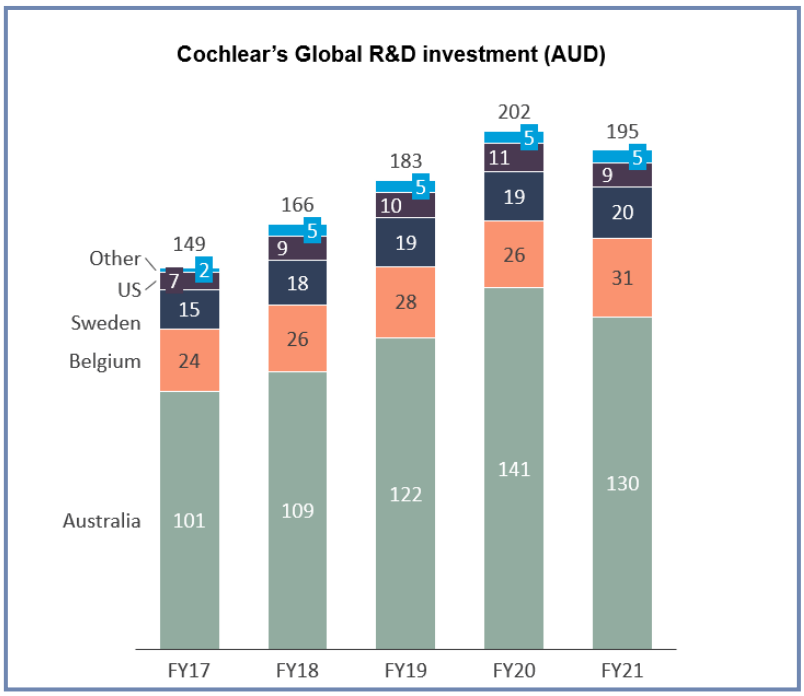
Applying the substantial activity requirement

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?

Cochlear maintains detailed record keeping systems in relation to individual R&D projects. This will include the details of what is incurred in Australia and overseas as well as what is third party and internal spend and is tracked as operational or capital expenditure. However, existing record keeping systems do not track these R&D expenses against what was incurred in relation to a particular aspect of a project that may lead to a patent or alternatively tracked against a patent once granted. The patent box shouldn't attempt to track allocation of expenditure directly to the patent as this is not a practical or realistic reflection of how business allocates investment in R&D. It should allow for a reasonable apportionment of eligible expenditure on the product incorporating the relevant patent.

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

The role of non-Australian R&D and the level of discretion companies have in whether they can invest more in Australia is different between the medtech and biotech/pharmaceutical sectors. Biotech/pharmaceutical development generally requires greater offshore activities as R&D progresses from pre-clinical, to Phase 1 through 3 clinical trials. Given Australia's small population size and patient cohorts, Phase 3 trials (sometimes requiring thousands of patients and hundreds of sites over several years) are generally conducted offshore and can often represent a significant portion of the spend on an Australian owned patent. This is less of an issue in medtech due to different regulatory requirements However, there are some jurisdictions that require clinical trials to be conducted 'in country' before regulatory approval. There is also an international trend toward more clinical evidence for medical devices being required by regulators, payers, and other stakeholders.



Definition of R&D

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)?

In principle the existing legal framework should be appropriate. Companies already collect substantial amounts of data in relation to the RDTI including expenditure against eligible activities conducted in Australia. However as noted in response to Question 12, offshore R&D is critical and/or unavoidable in some circumstances and these activities and expenditures should be included to the extent they are controlled by the Australian patent owner and linked to Australian R&D.

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

Costs incurred in Australia will generally be part of the R&DTI claims as well as those subject to an Advanced Finding (the mechanism for including overseas R&D activities and expenditure in the RDTI). However, given the cap on current claims for R&DTI, there will be locally incurred costs that have not been claimed as part of the R&DTI.

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?

A pragmatic approach must be adopted in determining what is qualifying expenditure. The UK system does not define how expenditure should be tracked and traced but makes it clear that a company must be able to demonstrate how the expenditure has been tracked and detail any significant adjustments to the methodology in subsequent years. For example, if the qualifying income is defined to include all of the product revenue from a particular product that incorporates a qualifying patent, then it is reasonable to also be able to track all of the R&D expenditure in bringing that product to market

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?

Typically, more than half a of our R&D is undertaken to enable commercialisation of a patent after the patent has been applied for. Without this 'post application' R&D many products would never make it to revenue generating stage. For example, more than half of our patent applications are filed as direct result of R&D that advances underlying technology (e.g., establishes that a technology is beneficial and practical), but it is typically not ready for implementation. Our product development teams then "take the baton" and devote significant R&D effort to readying the underlying technology (and the subject of the patent applications) for commercialisation.

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

A patent provides its owner with rights to prevent third parties from making and selling the owner's inventions. To leverage those rights, the owner must be able to identify use of patented inventions. Cochlear's practice is to pursue patents for manufacturing processes whenever the claimed method of manufacture is likely to be evident from the manufactured product. Manufacturing processes that are not detectable are typically not patented.

Implementation and start date

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)?

A patent box offered only on patents with a priority date 11 May 2021 would likely not be accessible by any Australian biotech company for several years. This approach would undermine the patent box policy objective of retaining and attracting R&D and commercialisation in the short and medium term. It is unlikely companies will be incentivised to invest more in Australia if they know they will not see any benefit for several years – particularly when the patent boxes available in other jurisdictions do not apply a date-based restriction on the eligibility of patents.

The patent box regime should allow for **all** eligible patents granted **as at the start date of the regime** (i.e., patents in existence on 1 July 2022) to be eligible patents for the Patent Box regime. A company would then elect into the regime to benefit. This election into the regime 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. This would be consistent with the UK patent box regime.

For any patents not yet granted at the start date there could be an additional election (provided a company has already elected into the regime) to allow the company to make a further election (on a patent by patent basis) to include profits, that arise in the period from application to the date the eligible patent is granted, into the patent box regime.

Under the UK patent box rules, this look back period is limited to the later of the start date of the regime, the date the patent application is filed, the date the company elected into the regime or 6 years before the right is granted.

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?

Yes, this would allow sufficient time to prepare for the regime. However, it will be necessary to ensure that there is robust consultation in relation to how the rules will be applied to ensure the information required is reasonably available.

Eligible revenue to enter the patent box

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

The Australian patent box should adopt the approach taken in the UK in this area to the greatest extent practicable. Qualifying income should include the total profit from the qualifying IP, less non-qualifying profit elements, such as routine profits and profits related to marketing assets. The UK patent box provides a precedent for this approach. It should include all income from sales of products which incorporate a qualifying patent, plus royalty income, gains on sales of patent rights and compensation for the infringement of IP.

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?

If a product incorporates one eligible patent or multiple eligible patents, the income from that product should qualify as eligible income. This is the approach taken under the UK patent box regime. The question of apportionment relates to the qualifying expenditure ratio, rather than the qualifying income ratio. A reasonable approach to apportionment of expenditure should be permitted, and likely linked to how R&D expenditure is tracked.

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)?

Cochlear's existing systems can track sales revenue by product item and category. These systems may need to be adapted to ensure the eligible revenue is streamed against the relevant patented product if the current systems are not aligned perfectly. Whilst this will require some effort it would not be prohibitive.

Subtraction of related patent expenses from eligible revenue

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

Under the RDTI regime Cochlear already tracks eligible R&D expenditure against eligible activities and maintains extensive records. Whilst this tracking may need to be adapted to ensure the eligible expenditure is tracked against the relevant patented income stream, this would not be prohibitive.

Treatment of losses and related offsets with the patent box

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?

Under the UK system, once a company has elected into the patent box regime (refer to response to Q18 above) all eligible patents that are granted to that company are included in the regime (unless a company later revokes their election). This means, any losses that may be attributable to an eligible patent must be included as patent box losses. These patent box losses must form part of the calculation to determine the overall patent box profits for the company. Patent box losses would therefore be required to be offset against patent box profits before the final patent box income amount is included in the patent box for income tax return filing purposes. The losses will therefore reduce any patent box profits.

The patent box should not distinguish between development or commercialisation with respect to losses. Once a company elects into the regime, all eligible patents granted to a company at that time are included, whether they are loss making or profit making.

This treatment of patent box losses is only for the patent box regime and the calculation of the overall patent box profit that would be subject to the reduced tax rate.

Administration and compliance

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

The regulatory burden in this respect is likely to be reasonably high but this would depend on the final drafting of the legislation. However, on the basis that medtech/biotech companies already maintain significant documentation for regulatory purposes and track expenditure and direct costs associated with product development for approvals and for claiming under the RDTI regime, any *additional* burden to access the patent box regime is likely to be able to be managed reasonably well.

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

An example would be the UK regime where the regime is aligned to the UK R&D credit regime as much as possible so as not to duplicate efforts, such as definitions around qualifying expenditure for the R&D credit regime and the patent box regime being aligned. It would be recommended that any features such as definitions around eligible

expenditure and evidentiary requirements are aligned as much as possible to the already existing RDTI regime in 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?

Please refer to our response to Question 5.