45 Poplar Road
Parkville VIC 3052

CSL.com
CSLBehring.com
Seqirus.com

16 August 2021

BY EMAIL: PatentBoxConsultation@treasury.gov.au

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

Dear Mr Fischer,

Patent Box Design - Response to Discussion Paper

Thank you for the opportunity to comment on the proposed design of a patent box regime, targeting the biotech and medtech industries in Australia.

We congratulate Government for introducing this important systemic, market-based, reform that should help to actively incentivise the onshore commercialisation of local medical research.

As you are aware, the long-term economic benefits of introducing a patent box should include onshore retention of much of the economic value associated with Australia's exploitation of intellectual property (such as royalty payments, licence payments, ownership of IP, etc.).

However, the design and management of the Australian scheme will be critical to ensuring it is workable, globally competitive, and drives the behaviour change needed to achieve the desired policy outcomes.

Importantly, given that it is focused on the medtech and biotech industries it must understand and reflect the time horizon(s) and expenditure profiles necessarily incurred in the development, registration, and exploitation of eligible patents (and associated intellectual property protections) in these sectors.

CSL notes that several of the broad design features, that appear to already be locked into the design of the scheme, may significantly challenge the workability and effectiveness of the scheme. These are noted below and expanded upon in the specific responses to questions posed by the consultation paper. The design features of particular concern include:

- ***An effective concessional tax rate of 17 per cent for companies on eligible profits from eligible patented inventions***

The global norm for the level of patent box tax incentives is 10%. A patent box offering a 17% rate is significantly higher than any offered by peer nations and would not be globally competitive. Companies making global locational decisions, calculating ROI, NPV etc, and where everything else is equal, are unlikely to choose a 17% rate over a 10% rate. Thus, the risk of a 17% rate is that the scheme fails to drive increased onshore exploitation of intellectual property.

- ***Only inventions claimed in standard patents granted by IP Australia, will be eligible***

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 sales and manufacturing, rather than where the patent owner is based.

More specifically, given that the Australian market is much smaller than the American, European, and Asian markets it is often more appropriate and advantageous to file patents in those markets, with Australia often being a lower priority. Ownership of the patent and the location of the R&D activities, is the key issue, as opposed to where it is filed.

When international patents are owned by an Australian-based company, most of the profit is taxable in Australia.

The Australian patent box should broadly encompass patents filed internationally but owned in Australia and developed from Australian R&D.

- ***Only patents applied for after the Budget announcement (that is, have a priority date after 11 May 2021), will be eligible***

The development timeframes in the biotech / pharmaceutical sector are extensive given the nature of the required R&D activities and compliance to regulatory frameworks. Patents can be filed at any stage of the biopharmaceutical development lifecycle but are generally first filed during the early research stage, with further filings made as a project progresses through development. In addition, the timelines for patent prosecution can often be quite protracted and in some circumstances may result in the commercialisation of a product before the grant of a patent. Generally, it can be between 5 – 10 years, or more, from when a patent is registered, to when it generates any revenue that might be eligible under a patent box regime.

It is likely that a patent box offered only on patents issued after 11 May 2021 would not be accessible by any Australian biotech company for several years.

Most 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 in are in products first commercialised after the announcement date (i.e., products that earn their first revenue after the specified date). This would assist with achieving the scheme's objective of IP developed in Australia being commercialised in Australia and enable benefits to be accessed in a more appropriate time frame.

- ***The concessional tax treatment will only apply to company profits from patented inventions in proportion to the amount of associated R&D that was conducted in Australia by the company***

The nature of expenditure incurred in biotech/pharmaceutical development, and Australia's small patient population, generally requires greater offshore activities as R&D progresses from pre-clinical, to Phase 1 through Phase 3 clinical trials. Phase 3 trials (often 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 patented invention.

The modified nexus patent box models, now in operation in many international regimes, are BEPS compliant and should provide a useful template for the Australian government. The

nexus approach under the OECD Guidelines allows all qualifying expenditure for activities undertaken by unrelated parties, regardless of the jurisdiction of the unrelated party. These guidelines also treat payments made through a related party to an unrelated party, but without a margin, as qualifying expenditures. CSL believes this should be a design feature of the Australian regime. Contract research organisations (CROs) are engaged to conduct most clinical trials for CSL (and other biotechs), and should be treated as qualifying expenditures where either incurred directly, or are a direct pass-through cost from a related overseas company. The purpose of a patent box regime is to encourage retention of IP in Australia as it is commercialised. The purpose of the R&D regime is to incentivise R&D activity in Australia – the purpose of the two schemes should not be conflated when designing the rules of the patent box scheme.

Responses to Questions from the Consultation Paper

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 understand and reflect the time horizon(s) and expenditure profiles necessarily incurred in the development, registration, and exploitation of eligible patents (and associated intellectual property protections) in these sectors. It should:

- Broadly encompass patents filed internationally but owned/taxed in Australia and developed from Australian R&D;
- Be offered to patents generating first revenue after 11 May 2021;
- Qualifying income should include all profits from sales of products covered by the patent, plus royalties and gains on sales of patent rights;
- Allow third party and related party pass-through R&D expenditure;
- Offer a 10% tax rate consistent with competing regimes;
- Acquired IP should be eligible. Many global regimes treat acquired as eligible, and the qualifying R&D expenditure is calculated in the nexus ratio calculation;
- In the event acquisition costs or outsource costs are not eligible, consider applying an uplift percentage to eligible R&D, as per the OECD guidelines.

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

Assuming companies elect to seek patents in Australia, then it will most likely include seeking a standard patent, and not just an innovation patent. Where CSL has Australian patents they are 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?**

Yes. The scheme can choose to recognise patents from certain other countries/territories which have been "subject to substantive examination in front of a patent office", i.e. from nations that offer similar assessment rigour to IP Australia. For example, patent prosecution highways (PPH) are in place between Australia and multiple jurisdictions (see

https://www.wipo.int/pct/en/filing/pct_pph.html). The PPH is intended to reduce duplication of effort by allowing the patent office in a country of second filing to take advantage, at least partially, of the work of the patent office in the country of first filing.

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

Sovereign risk and the likelihood of substantive regulatory change are enormously material to a company making a long-term investment decision based on an Australian patent box. This must be recognised in the legislation and include appropriate grandfathering assurances.

5. **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?**

Yes. Detailed record systems are maintained 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. However, the spend cannot track what was incurred in relation to particular aspects of a project that may lead to a patent.

The location of where the expenditure is incurred should not be a relevant consideration for the nexus calculation. For example, CSL outsources the running of pre-clinical and clinical trials. Pre-clinical trials will often involve the use of CROs that can be based in Australia or overseas. For clinical trials, while first in human trials are often conducted in Australia, Phase II-III trials will generally be conducted by overseas based third parties. This should still be treated as qualifying expenditure.

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

The nature of expenditure incurred in biotech/pharmaceutical development generally requires greater offshore activities as R&D progresses; e.g. from early stage research to formal pre-clinical studies, and then to Phase I, II and III clinical trials. Given Australia's small population size and patient cohorts, Phase III trials (often requiring thousands of patients and hundreds of sites over several years) are generally conducted offshore and can represent a significant portion of the spend on an Australian-owned patent. The example below is a high-level analysis of CSL's R&D expenditure on product development and shows that our Phase III trials account for, on average, around 50% of relative spend:

PHASE	~COST (USD)	% TOTAL
Research	$25m	13%
PD & GLP Tox	$25m	13%
Phase I	$20m	11%

Phase II	$25m	13%
Phase III	$90m	47%
Registration	$5m	3%
Total Program Cost	$190m	

**Phase I / II / III estimates based on the average trial costs within our R&D portfolio (per a sample data set). Relative % spend based on costs through Regulatory filing (does not take into consideration Phase IV / post-marketing commitments etc. Internal labour accounts for approximately 25% of the total program spend.*

Clinical trials comprise a significant component of the overall costs of developing a product. CSL develops the parameters of a clinical trial design but, like most biotechs, outsources the running of clinical trials to experienced Contract Research Organisations (CROs). These third-party costs comprise a significant component of overall costs and can be in the region of **30%** of overall annual R&D portfolio costs.

Recognising the size of the Australian population and the need for offshoring the majority of clinical trial activities beyond Phase 1 or early Phase 2 studies, an Australian patent box must allow both third party expenditure and pass-through third party R&D expenditure to be an attractive, competitive regime. This is in line with the OECD BEPS principles.

7. **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. However, provision must be made to ensure that allocation of costs, on a reasonable basis, will be accepted.

CSL has significant infrastructure costs associated with its R&D activities. These are necessary costs for an organization with global annual R&D costs in excess of US$900m and are necessarily incurred as part of developing patented inventions. Costs of this nature include;

i. Cross Product/Portfolio - costs reflecting platform development, new product development or lifecycle management costs that cannot be attributed to a single therapeutic area or project, but support multiple projects and programmes in the portfolio. These costs represent c15% of our annual global R&D spend and a reasonable basis for allocating these costs should be permissible.

ii. Operations - costs reflecting costs of the R&D operations, systems, safety and control environment including pharmacovigilance, regulatory affairs and strategic operations.

iii. Infrastructure - costs reflecting facilities, license costs and other overheads supporting delivery of the R&D portfolio.

45 Poplar Road
Parkville VIC 3052

CSL.com
CSLBehring.com
Seqirus.com

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

Not all expenses related to the development of products that have Australian-owned patents will be subject to R&D Tax Incentive (RDTI) claims. For example, foreign incurred R&D expenses that contribute to the development of a product are generally not the subject of RDTI claims[1]. This includes third party and related party costs (both pass-through and costs incurred directly by related parties).

The costs incurred in Australia will generally be part of the RDTI claims. However, given the cap on current claims for RDTI, there will be locally incurred costs that have not been claimed as part of the RDTI.

9. 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 defining 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 has a qualifying patent, then it is reasonable to also be able to track all of the R&D expenditure in bringing that product to commercialisation.

10. 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? 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)?

The development timeframes in the biotech / pharmaceutical sector are extensive given the nature of the required R&D activities and compliance with regulatory frameworks. Patents can be filed at any stage of the biopharmaceutical development lifecycle but are generally first filed during the early research stage, with further filings made as a project progresses through development. Generally, it can be 5 – 10 years or more from when a patent is registered to when it generates any revenue that might be eligible under a patent box regime.

It is likely that a patent box offered only on patents with a priority date after 11 May 2021 would not be accessible by any Australian biotech company for several years.

11. 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.

[1] While there are specific circumstances in which a R&D TI deduction can be claimed for expenditure related to overseas activity, CSL does not currently claim any such costs.

45 Poplar Road
Parkville VIC 3052

CSL.com
CSLBehring.com
Seqirus.com

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

Manufacturing processes are often the subject of their own patents.

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

Qualifying income should include the total profit from the qualifying IP, less the non-qualifying profit elements, such as finance results. It should include all income from sales of products which are covered by a qualifying patent, plus royalty income, gains on sales of patent rights and compensation for the infringement of IP.

14. **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 has eligible patents, the income from that product should qualify as eligible income. 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 linked to how R&D expenditure is tracked.

15. 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)?

CSL's current systems provide sales revenue by product. If a product has one or more eligible patents, the income from that product in total should qualify as eligible income. The question of apportionment must relate to the qualifying expenditure ratio, rather than the qualifying income ratio.

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

Expenditure is tracked by R&D project. These costs can be reviewed as costs incurred directly, costs charged by third parties and/or costs charged by related parties. It is also possible to determine what costs have been incurred directly by the project, and also what costs have been allocated to the project. Allocated costs represent the share of R&D infrastructure, R&D operations and R&D cross product/portfolio costs required to support continued development of patented inventions (as detailed in the response to question 7.)

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

This is difficult to answer until the scheme has been designed. However, if an appropriately broad-based approach is designed to determine both revenue and relevant expenditure, the regulatory burden should not be large. Companies already have robust processes for recording direct costs associated with developing a product, and for allocating costs to projects. These will be subject to audit.

45 Poplar Road
Parkville VIC 3052

CSL.com
CSLBehring.com
Seqirus.com

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

Australia needs a flexible, pragmatic, globally competitive and attractive principles-based system to be workable for biotech companies and to achieve the Government's policy objective of incentivising the onshore commercialisation of medical research. An overly onerous, or worryingly punitive, regime will be unworkable for companies and ineffective for Government.

Internationally, other Governments have achieved their policy priorities with patent box regimes and we strongly recommend that the Australian system adopt many of the existing parameters within either the UK or the Swiss models. In particular, adopting a principles-based system design that permits some flexibility for companies to be able to reasonably demonstrate how costs and revenues have been apportioned.

CSL would be pleased to participate in further consultation and discussion as needed.

Please contact CSL Director of Public Policy, Anna Schulze (anna.schulze@csl.com.au 0438 084 045).

Yours sincerely,

Ms Aoife Deane
CSL Global Head of Tax