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Patent Box

Discussion paper on policy design – July 2021

Submission by Telix Pharmaceuticals Limited

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). A key focus of Telix is the development of products that use antibodies as targeting agents. Telix is headquartered in Melbourne, with international operations in Belgium, Japan, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA, and has been granted Priority Review status by the Australian TGA. Telix is also progressing marketing authorisation applications for Illuccix® in the European Union and Canada.

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?

Countries such as the UK and Belgium have relatively mature patent box regimes. The key features of these patent box regimes which Telix considers to be of importance include:

- The patent box regime is applied on a project-by-project basis or a product-by-product basis rather than a patent-by-patent basis. As we discuss further below, a patent-by-patent approach requires an unnecessarily complex enquiry into the proportion of income which is due to a particular patent. This is particularly the case for the medical and biotechnology fields where multiple patents may be relevant to a particular product.
- The relevant R&D expense which is incurred in a jurisdiction is assessed over the life of the project or product rather than only the expense incurred in getting the project to a position where the patent has been filed. Ideally, the relevant R&D expenses should include Phase I - III clinical trials required for product registration, as well as any Phase IV clinical trials that may be required support product funding and reimbursement. Patents are often applied for early in the life of the project when little expense has been incurred compared to the overall

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cost of developing a product. Telix therefore consider this broad definition of relevant R&D expense to be necessary in order to practically incentivize R&D to be conducted in Australia. The regime requires a patent that applies to the project or product to be granted in the relevant jurisdiction, in this case Australia. This avoids the question of whether patents in other jurisdictions should be considered.

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?

Medical and biotechnology companies with domestic R&D operations will typically apply for patents in jurisdictions which are expected to be major markets for their products. Typically, this will at least include the USA and Europe. Australia is often included in the list of countries but may not be as it is not a commercially significant market for most products. Telix would expect that any Australian patent box regime should require that the company seeking to rely on the regime owns or has a license to an Australian standard patent that is relevant to the product.

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?

We do not consider the answer to this question is required if a regime is adopted where a relevant Australian patent must be owned or licensed in order for the regime to apply. However, to answer the question, generally speaking, patents in major jurisdictions such as the USA and Europe will generally have a claim scope that would be accepted by the Australian Patent Office.

Targeting medical and biotechnology

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

As discussed above, Telix considers that the patent box regime should be applied on a product-by-product or project-by-project basis. If that is the case, then Telix considers that the patent box regime should apply to projects conducted with the primary intent of seeking regulatory approval(s) of a product from a body or bodies such the US FDA (Food and Drug Administration) or the Australian TGA (Therapeutic Goods Administration).

The International Patent Classification would provide a basis to assess whether particular patents are in the medical or biotechnology fields.

Alternatively, established and widely applied regulatory definitions of drugs, medical devices and biologic agents may be used to define specific product categories within the medical and biotechnology sectors that would be eligible for the patent box regime, e.g. US FDA's Classification

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of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff, available at: https://www.fda.gov/media/80384/download

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?

The core concept should be that the project is directed to improvements in human (or animal) health and, in particular, to the development of diagnostic and therapeutic products. Such improvements in humans may be achieved through either:

1. Improved clinical outcomes in the primary or tertiary care setting (delivered by new diagnostic or therapeutic products), or
2. Improved public health outcomes (delivered across specified human populations)

Low emissions technologies

Telix considers that any patent box regime should be expanded to cover not only the medical and biotechnology sectors and the clean energy sectors but should be a broad-based regime to incentivise Australian R&D.

This clean energy field is not directly relevant to Telix's business or expertise. We have not answered Questions 6 to 10.

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?

As discussed above, Telix considers that the regime should apply on a product-by-product or project-by-project basis. If that is the case, then existing record keeping systems are adequate and sufficiently robust to accurately distinguish between R&D expenses incurred in Australia and elsewhere. At present, record keeping systems are not adequate to calculate the proportion of R&D related to a patented invention.

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

At many levels Australia lacks the infrastructure and expertise both in the public and private sectors to carry out the R&D required by a company such as Telix. Accordingly, a significant amount of R&D is carried out overseas. Telix relies significantly on unrelated parties such as universities and medical

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research institutions, CRO (contract research organisations), CMOs (contract medical organisations) to conduct basic research, manufacturing and clinical trials.

We consider that where R&D that is critical to the development of a product cannot be conducted in Australia, then that R&D should be treated as if it were Australian R&D for the purposes of the patent box regime as it would be for the R&D incentive regime.

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)?

Yes. Telix has lodged R&D Tax Incentive Applications in the last two years, describing the R&D investment activities within Australia and overseas on various initiatives.

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

Telix has been successful in demonstrating the majority of its R&D inventions to R&D claims in the last few years.

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?

As discussed above, there is much value in taking advantage of the UK's experience in administering their patent box regime.

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?

The amounts incurred in R&D in developing a product to the point where a patent can be applied for are trivial when compared to the amount of R&D required in clinical testing, clinical trials and the manufacturing campaign required to take the product to a regulatory approval. A reasonable estimate would be $2-3 million to conduct enough R&D to file a patent with subsequent R&D costing up to $100 million, particularly where a large-scale phase III clinical trial is required, and the product incorporates an antibody.

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

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It is not common to manufacture antibody products such as Telix's in Australia. These processes can be subject to their own patents but not necessarily. Composition of matter (directed to the pharmaceutical itself) and method of treatment patents are regarded as more valuable and are inevitably filed.

Implementation and start date

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)?

Telix regard this a significant issue in the implementation of the patent box regime. Typically, in the development of a new therapeutic or diagnostic pharmaceutical, it will take in the order of 10 years from the date of filing of the initial patent to regulatory approval. Often, the time frame is much longer. Telix would advocate for the regime to apply to any patent whenever filed.

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?

If a regime is adopted that relies on a project-by-project or product-by-product basis then little effort will be required to prepare for the regime. Clearly, the regime will incentivize new R&D to be conducted in Australia. This would come into effect more quickly if the regime applied to patents with an earlier priority date than 11 May 2021.

Eligible revenue to enter the patent box

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

Each of the revenue forms listed are legitimate ways of exploiting a business' IP and should be subject to the patent box regime, so that the tax benefits derived from the patent box do not adversely distort commercial behaviour.

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 UK and Belgium patent boxes apply certain rules to the assessment of eligible income and we would submit that these should be considered by Treasury.

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?

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This is extremely common in the medical and biotechnology sector and there is no simple way to differentiate the revenue that can be apportioned from one patent to another. This is, in part, why Telix endorse a project-by-project or product-by-product approach. Indeed, failing to do so would possibly disincentivise companies from perceiving value from a patent box approach as the administrative burden of a commercially robust "patent thicket" would be high.

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)?

We would point Treasury to the mechanisms that are applied under the UK and Belgium schemes. In terms of our systems, Telix has advanced Enterprise Resource Planning (ERP) general ledger financial systems, which would be able to record the relevant transactions in an appropriately specific manner.

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?

We would point Treasury to the mechanisms that are applied under the UK and Belgium schemes. In terms of our systems, Telix has advanced ERP general ledger financial systems, which would be able to record the relevant transactions in an appropriately specific manner.

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?

We would point Treasury to the mechanisms that are applied under the UK and Belgium schemes. In terms of our systems, Telix has advanced ERP general ledger financial systems, which would be able to record the relevant transactions in an appropriately specific manner.

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?

This very much depends on the details of the patent box regime that is ultimately adopted.

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

The UK tax system has a similar R&D incentive scheme to Australia, and this is combined with a patent box regime. It would be useful to consider this regime in detail when looking to implement the Australian patent box regime.

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?

Evidence of consultation with regulatory authorities and/or evidence that the R&D is being conducted with a view to ultimately seek approval for a diagnostic or therapeutic product.

Other considerations

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

Not at this stage. However, Telix intends to make further submissions as the details of the patent box regime to be adopted are more fully elucidated.

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