Response to patent box discussion paper- July 2021.

11 August 2021

I have worked in the medical products industry for over 30 years. I am currently a director in AusIndustry's Entrepreneurs' Programme. The programme has provided business advisory and funding to over 500 medical product SMEs and start-ups over the last four years.

The paper makes frequent references to 'standard patents'. The largest user of patents are the medical technology, pharmaceutical, and biotechnology industries. This is because of the extremely large investment needed to commercialise a new product. For the same reason, companies in these sectors are frequent users of the PCT system. The comments that follow assume that a standard patent granted in Australia and an Australian granted patent that has come via the PCT system both provide equal access to the incentive.

One of the stated goals of the incentive is retaining ownership of intellectual property in Australia. There are three commercialisation options for an IP owner: sell, licence or develop a business. Within medical products industry, licensing is relatively common. In such cases, it's not just the owner of the patent that is important. The benefits derived from the incentive need to flow back to the Australian business taking on the financial risk that comes with attempting to commercialise medical inventions. The licensing agreement between the parties ensures benefits flow back to the original inventor/owner.

The goals appear to be associated with commercialisation of innovation rather than retaining manufacturing. Indeed, there are very few references to manufacturing in the document. Given the importance of manufacturing to Government, it might be beneficial to build greater consideration of this national benefit into the incentive.

The tax rate treatment applies to the proportion of R&D conducted in Australia. The largest component of R&D costs in the pharmaceutical/biotechnology industry results from clinical research. Companies conduct clinical research where you can find patients. For example, it would be folly to attempt to conduct a Covid vaccine clinical study in Australia because of the low prevalence of disease here. This approach to tax treatment is likely to reduce the attractiveness of the benefit in the medical products sector for reasons beyond the control of the applicant.

Some of the mechanisms for determining eligible and non-eligible expenditure referred to may become complex. Managing complexity creates a cost burden that may ultimately reduce the attractiveness of this incentive. This will disproportionately impact SMEs compared to larger businesses where administration and compliance activity needs to be outsourced. The IP industry is better placed to propose how these mechanisms might work, but a design principle should be to simplify them wherever possible.

Linking the scheme to patents that have a priority date after a fixed date seems sensible but setting this fixed date in May 2021 is not ideal for the medical products industry. There are a number of implications

- It can take many years to bring a new medical product into the market. Cash flow pressures and opportunity costs force SME to make difficult decisions concerning their long-term investments including their patent estate. One of the more important aspects of the R&D Tax incentive, is that the benefits flow back to the business within a reasonably short

timeframe. While it is true that medical products tend to be protected by multiple patents, some of which are granted late in the development process, a mechanism may be needed to ensure that the incentive remains equally attractive to businesses developing new products that have a very long R&D pathway and those much closer to market commercialisation.

- Linking the benefit to the priority date also has a downstream impact. As medical products consume a considerably larger portion of patent life to commercialise the product compared to other sectors, the period over which they can enjoy the incentive will be shorter. In recognition of this reality, the regulatory system can use exclusivities to incentivise innovation.

The paper asks if the incentive should apply to royalties and license fees. Licensing revenue generated before a product is commercialised should be eligible for the incentive. In many parts of the sector, the introduction of a new product to the market can only be achieved through partnering with a larger entity that has the financial resources to support late-stage clinical studies. As a result, the companies that successfully execute a licensing arrangement are exactly the businesses we should be supporting. After commercialisation, royalties and milestones should continue to be eligible but in addition, the manufacturer of the product could also benefit from the incentive to the extent that they undertake technical and commercial risk to bring about domestic production of all or part of the product in Australia. This might act as an additional incentive supporting the growth of Australian manufacturing.

To benefit from the patent box you need to use patents. Australians engage in patents well, particularly when it comes to medical products. Outside this sector, SME engagement in the patent system by manufacturing businesses is not as strong as in other nations (1). Incentives like the patent box tend to be better integrated into business as usual if there is also firm-level advisory support for their use.

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(1) Patent accessibility review. Emeritus Professor Raoul Mortley (February 2021).