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SpeeDx's submission to the Australian Government's Patent Box consultation

Background on SpeeDx

SpeeDx is an Australian diagnostic company, with over 100 employees, that has developed a molecular diagnostic technology that enables rapid development of highly specific and sensitive multiplex molecular tests using bulk manufacturing processes. SpeeDx's technology is uniquely placed to efficiently detect multiple targets, such as drug resistant disease strains of virus variants at the same time.

Currently, SpeeDx has been granted 122 patents worldwide and has 57 patents pending. All SpeeDx's patents have been a result of R&D conducted in Australia.

Key recommendation

The Australian Patent Box includes not just "new" IP (lodged after the budget announcement) but existing Australian IP.

Discussion around key recommendation

If the proposed Patent Box regime is to specifically incentivise and encourage commercialisation of Australian IP in the medical and biotechnology sector, it must reflect the long and complex commercialisation pathways characteristic of the industry. Furthermore, to achieve the goal of retaining the ownership of eligible patented inventions in Australia, the Patent Box should extend to IP that currently exists in Australia which is often at high risk of being sold and/or moved offshore.

SpeeDx case study

To provide an example on the pathway to commercialisation for an Australian medical diagnostic technology developed from R&D undertaken in Australia, please see below an outline of the commercialisation and R&D pathway for our technology.

Platform technology: PlexPrime®

Product description: PlexPrime® is a novel method for generating nucleic acid amplicons which are distinctly different from the parent sequence. This technology forms the basis of our mutation detection approach which enables our diagnostics to efficiently and reliably detect drug-resistant disease strains or virus variants.

The timeline for submitting a provisional patent, full patent and then bringing products to market based on this IP is outlined below.

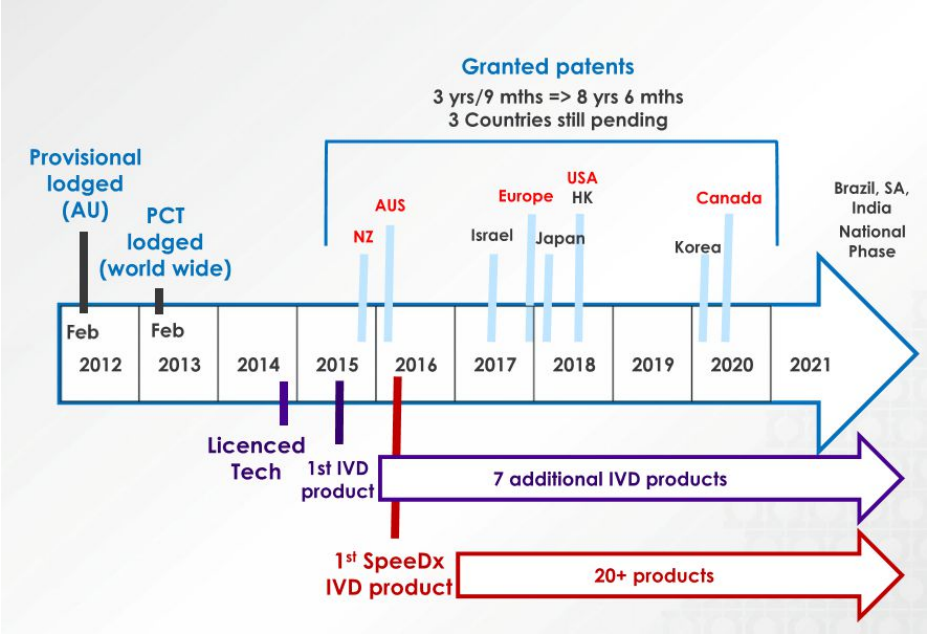

Figure 1: patenting and commercialisation timeline for a medical diagnostic technology

Key takeaways

- It took **3 years and 9 months** from when the provisional patent was lodged to when the first patent was granted (this was considered fast). Worldwide patents are still being granted in relation to the PlexPrime technology.
- It took **2.5 years** from when the provisional patent was lodged to when the technology was first out-licensed. Out-licensing didn't require SpeeDx to develop and commercialise a product.

- It took **4 years** from when the provisional patent was lodged to when SpeeDx launched its first product using the PlexPrime technology.
- SpeeDx continues to develop new products based on this platform technology.
- Indeed, SpeeDx's PlexPCR SARS-COV-2 test which was launched in 2021 is based on the PlexPrime® technology.

Discussion points

- SpeeDx's products are based on a platform of already-patented technology. As such, expected benefit under the current Patent Box design would be extremely limited, even for new products developed.
- The proposed Patent Box design currently does not provide any incentive to keep SpeeDx's headquarters in Australia, even though SpeeDx's IP is a result of R&D undertaken in Australia.

As the legislation is drafted, it is highly unlikely that commercialisation of Australian IP within the short to medium term in the medical and biotechnology sector will be incentivised by the proposed Patent Box policy. Furthermore, the proposed Patent Box policy will not discourage selling of existing Australian IP to companies who would then shift the IP to an overseas jurisdiction, which is a common occurrence in the sector.

Responses to other questions in the Government's Patent Box discussion paper

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

It is very common for some R&D activities to be undertaken overseas, in collaboration with other entities and/or with contract research organisations in the medical and biotechnology industry. This is due to a number of factors including:

- The need for highly specialised equipment or facilities for a particular stage of the R&D process.
- Need for highly specialized inputs into the R&D process
- Access to specialized skills for a particular stage of the R&D process
- Access to a very specific sample population for testing of products or a hypothesis

For SpeeDx, while all assay and product development is done inhouse, it is very common for SpeeDx to collaborate with other entities to test a new product within a specific sample population. In this case, SpeeDx would incur the expense for these activities and retain any IP generated.

Recommendation: To accurately reflect how R&D activities need to be undertaken in the medical and biotechnology industry, particularly in Australia, qualifying R&D expenditure should include all expenditure which an entity incurs as per the 'by and for' provisions of the R&D Tax Incentive. Additionally, this should include expenditure where R&D activities need to be done overseas but where the Australian tax paying entity bears the financial risk of this activity and owns the IP generated. SpeeDx recommends that where R&D expenditure incurred on activities undertaken overseas meet the requirements set out under the R&D Tax Incentive's overseas finding processes, then it should be included as qualifying R&D expenditure under the Australian Patent Box regime.

Question: 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?

- SpeeDx continually undertakes R&D activities, and the patent box regime would not change this. However, depending on the benefit of the regime, it may influence where future R&D activities are undertaken (i.e. in Australia or overseas).

- More detailed compliance requirements are required to determine how prepared SpeeDx's current internal reporting systems are for the new regime. However, the highly restrictive design of the policy suggests that significant internal effort would be required to prepare for the regime.

Question: 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?

Removing the criteria for only "new" IP to be included in the qualifying R&D percentage would significantly reduce the complexity of calculating the R&D fraction.

Question: 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?

As SpeeDx's products are based on already patented platform technology, significant R&D effort is undertaken post patent for each new product that is released to the market.

Question: 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?

Due to the industry's long R&D timeframes, it is common for medical and biotechnology SME companies to be in tax losses for a number of years after they have commercialised a technology. For the patent box regime to remain as an incentive for these companies, **we recommend** that a similar tax approach to the R&D Tax Incentive be adopted. That is, the patent box tax incentive should be a refundable offset for SMEs. No undue complexity or integrity risks should be introduced to the system if it aligns with the same tax arrangement as the existing R&D Tax Incentive regime.

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

Greater incentive needed in policy design to drive change

The current 17% concessional rate is not a sufficient incentive to change existing R&D and commercialisation behaviour in the Australian landscape. Reasons for this include:

- There are significant commercial barriers for commercialising in the medical and biotechnology sectors in Australia including, distance to key markets, high labour and manufacturing costs and skill shortages. Monetary incentives need to be significant to overcome these barriers.
- The current Patent Box policy design places many restrictions on 'qualifying R&D expenditure" which will in turn result in a low R&D fraction and therefore relatively low quantum of revenue eligible for the concession.
- 17% is not competitive within the global landscape for patent box regimes
- 17% tax rate is not significantly lower than existing corporate tax rate which would likely be 25%
- High expected compliance costs will likely outweigh the 8% (25%- 17%) tax benefit on qualifying revenue

Incentivise onshore manufacturing

The Patent Box regime could also improve the Australian medical and biotechnology commercialisation landscape by including manufacturing expenditure as qualifying expenditure or providing a better concessional tax rate for companies who manufacture their product in Australia (similar to the principle of applying a higher R&D Tax Incentive rate based on R&D intensity). This would also align with other government policy to boost advanced manufacturing in Australia.

Concluding remarks

In principle, SpeeDx is very encouraged and supportive of the introduction of an Australian Patent Box regime and see its potential as a powerful incentive for companies to develop and commercialise medical and biotechnology technologies in Australia. However, in its current form, the proposed Patent Box provides **little to no incentive** to commercialise technology in Australia or retain IP in Australia. As such we strongly recommend and hope that the Government considers the key points highlighted in our responses as well as engages in further discussions with industry in relation to an effective policy design.