

Article Information

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Biotechnology and the R&D tax incentive - current issues

There are some recent developments in the RDTI regulatory space that it is important for biotechnology companies to be across to ensure that future RDTI claims can be supported.

Biotechnology has many applications in the health, agriculture, marine, industrial and environmental sectors.

Whilst there are some large players in the field the sector is mostly made up of small and medium size companies many of which are in the pre-revenue and pre-market stage.^[1] It has been a rapidly growing sector, and one which invests heavily in research and development (**R&D**) with high return for the economy – \$2.18 per foregone dollar of tax revenue based on a report released in 2023.^[2] A strong positive gain. In dollar figures it is estimated that between 2011 and 2021 the research and development tax incentive (**RDTI**) support for the biotech industry increased Australian GDP by an estimate \$9.1 billion and supported 3,445 jobs.^[3]

There are some recent developments in the RDTI regulatory space that it is important for biotechnology companies to be aware of.

The first, that funding and asset ownership structures ought to be carefully considered and revisited. That what has been accepted in the past may not be accepted into the future.

The ATO has increased its focus on the integrity provisions within the RDTI program, putting into focus that structures that:

- depend on sharing staff across a group, related party loan funding, related party licensing arrangements or related party share subscriptions to fund R&D increase compliance risk.
- allocate financial risk to an entity other the R&D entity, or enable intellectual property ownership to be shared with another entity increase compliance risk.

The above does not mean that those structures can never be used. Rather, that increased care needs to be taken to ensure the implications for the RDTI are fully understood, that the claims are made in the right entity and steps taken to ensure that the claiming entity has the requisite control, risk and ownership to be able to claim the RDTI.

The second, the need to ensure that transfer pricing studies and treatment and RDTI treatment align and that there is adequate and clear documentation in place to ensure that where the R&D is undertaken can be evidenced as being Australian or overseas with the requisite control, risk and ownership again sitting in the Australian entity. On this front we are aware of some confusion in the market resulting from the ATO's release of TR 2023/5.

The next, confirmation from the Tribunal that for the purpose of the RDTI living things can be considered to be the subject of an experiment when rather than being left to grow naturally without intervention, they are instead subjected to a controlled method or process.^[4] A positive for RDTI eligibility overall, but also a decision that means feedstock adjustments reducing the benefit could apply quite broadly in the biotechnology space.

Finally of course all of the usuals: the need to have a hypothesis and systematic process, to have documentation and substantiating materials and to ensure that your technical personnel and tax personnel are working from the same definitions in making decisions and capturing records. Whilst often underrated, having RDTI specific governance policies in place can go a long way to achieving that objective.

Biotechnology companies should consider reviewing their existing structures and record keeping practices for RDTI risk, seek advice where there is uncertainty and consider implementing RDTI specific governance frameworks to support future claims.

[1] “Economic impact of the Research & Development Tax Incentive for the biotech industry” October 2023, Deloitte Access Economics accessible via <https://www.ausbiotech.org/news/new-report-quantifies-the-impact-of-rd-tax-incentive-rdti-in-australias-life-sciences-sector>.

[2] “Economic impact of the Research & Development Tax Incentive for the biotech industry” October 2023, Deloitte Access Economics accessible via <https://www.ausbiotech.org/news/new-report-quantifies-the-impact-of-rd-tax-incentive-rdti-in-australias-life-sciences-sector>.

[3] “Economic impact of the Research & Development Tax Incentive for the biotech industry” October 2023, Deloitte Access Economics accessible via <https://www.ausbiotech.org/news/new-report-quantifies-the-impact-of-rd-tax-incentive-rdti-in-australias-life-sciences-sector>.

[4] *GQHC v Commissioner of Taxation* [2024] AATA 409.