Response to the Higher Education Research Commercialisation (HERC) IP Framework Consultation Paper issued by the Commonwealth Department of Education, Skills and Employment

15 October 2021

Background

BioCurate Pty Ltd (**BioCurate**) is a joint venture company established by the University of Melbourne and Monash University – with the support of the Victorian government - to identify promising biomedical research and help accelerate its development.

We are operationally independent from our shareholder Universities, with a team that brings decades of scientific and commercialisation expertise.

Given BioCurate's mandate and the experience of our management team, our views below are from the perspective of a commercialisation partner (**CP**) that is frequently negotiating commercialisation deals with Universities and higher education research organisations (**ROs**). We acknowledge that our views as a CP may differ from those of our shareholders (ROs) on certain issues.

In negotiating commercialisation deals with ROs, we have identified a number of common themes and issues which in our view hinder the ability to successfully commercialise RO research. Our submission highlights these issues and suggests ways they may be addressed.

Our submission does not seek to respond to all of the discussion questions in the HERC consultation paper. However, our submission is broadly relevant to questions 2, 3, 9, 10 and 11 of the HERC paper.

Submission

Issue 1: *Standard documentation received from ROs is drafted heavily in favour of the relevant RO, and the process to agree on terms is extremely inefficient and time consuming.*

We endorse the proposal to standardise relevant commercialisation documentation. However, for this to be successful - the standard documentation must provide more favourable terms than is typically contained in RO standard documentation if a CP is investing significant time and funds, including:

- IP created as a result of CP funding at commercial rates (**Project IP**), even if created by the RO, should be owned by the CP;
- there should be a clear & consistent hurdle/trigger for the assignment of the licensed IP to the CP (such as a level of expenditure on developing the technology or achieving an agreed development milestone). To encourage CP investment the hurdle for IP assignment should not be more than 2-3x the pre-money valuation;
- given the significant expenditure and risk taken on by a CP, the rights for a RO to terminate should be appropriately limited so that a RO cannot exit the arrangement easily and require an assignment back of the licensed IP and Project IP;
- in relation to any obligations on the CP to assign the licensed IP (and Project IP) back to the RO on termination, this should not be mandated and there needs to be flexibility to provide for circumstances where this is not appropriate (for example, if there is a third party that has contributed

funding - the Project IP should be an asset that should be dealt with through the usual winding up of the venture);

- anti-shelving provisions should be optional, and if present tied to spend, as they are not appropriate in all circumstances and industries. For example, if a pharmaceutical company has already paid a substantial sum for an exclusive licence to patented technology - it may have valid commercial reasons as to why it is not actively commercialising or developing it for a prolonged period and therefore not necessarily subject to default anti-shelving provisions;
- reporting obligations need to be high level, infrequent (e.g., annually at the most) and flexible (and not prescriptive and resource intensive);
- the application of the publications regime should apply to publications relating to the licensed IP both inside and outside the licensed field, given that publications outside the field can still inadvertently disclose valuable IP or confidential information. In relation to Project IP which is confidential information, the CP should be able to restrict publication in its absolute discretion (as it has paid for such IP to be created);
- technology development and commercialisation decisions (including who the licensed IP can be sublicensed to, how and on what terms) need to be the responsibility of the CP and not subject to extensive requirements and prior RO approval (noting that the CP is providing the funding, generally has more commercialisation expertise and is also best placed to make these decisions). For example, extensive requirements with regard to sub-licensing may limit the ability of the CP to do deals with a third party which is a barrier to further commercialisation; it may not be financially viable nor commercially desirable (e.g., for quality or time to execute reasons) for the CP to conduct further development work at the RO or in the researcher's lab; CPs can consult and update ROs in relation to such decisions;
- liability and indemnities should be balanced such that each party takes on a reasonable level of risk in relation to those matters reasonably within its control (rather than the entirety of the risk being placed on the CP). For example, our experience has been that RO liability is capped whereas the liability of the CP is not; indemnities are in favour of the RO and extremely broad; RO warranties with respect to encumbrances on Background IP should be absolute as this is within the RO's control and breach of this warranty should not be subject to a cap on liability.

Issue 2: *RO teams are often not restricted from shopping around the opportunity to third parties while a CP is conducting due diligence.*

Given the high costs of undertaking due diligence (particularly in the biomedical fields), the standard documentation for options to licence should protect the CP making this investment by:

- being provided with exclusivity during the due diligence period (with an obligation not to shop the opportunity); and
- providing certainty as to the terms of the licence, should it be exercised (rather than a first exclusive right to negotiate, which lacks certainty of terms). While it is generally not feasible for parties to negotiate the terms of a final licence where the CP is only entering into a limited option to undertake due diligence, this becomes feasible in the event there is standard HERC framework documentation for commercialisation licences that could be relied upon for this purpose.

Such terms would incentivise more CPs to conduct due diligence on a greater number of projects and increase investment in early-stage research.

Issue 3: *The valuation that ROs and individual researchers place on early stage and under-developed technology is not in line with market expectations, particularly in fields (such as biomedical) where the costs to get a product to market are so high and the chances of success are very low.*

The framework should provide guidelines to assist in determining an appropriate pre-money valuation and/or reasonable royalty / return to the RO which also factors in the significant investment and risk taken on by a CP in taking early-stage technologies to market. More reasonable pre-money valuations in line with market expectations will encourage follow-on investment which is critical to ultimate commercialisation of the licensed IP.

Issue 4: *ROs insist on extensive ongoing research rights both inside and outside the field. There is the potential for such ROs to create competing technologies which adversely impact the licensed IP.*

While we understand the importance of academic freedom and the ability to conduct future research, this needs to be balanced with the risk that such activities can undermine the value and potential of the licensed IP (either by unintentionally raising safety issues, divulging confidential information and publishing data that limits the ability to patent licensed IP or improvements to it). The standard documentation should provide:

- that improvements made by the RO to the licensed IP should be automatically included in the licence to avoid the possibility that these improvements, if subsequently licensed to a competitor, undermine the value of the originally licensed IP; and
- restrictions on the RO sub-licensing to third parties to conduct research in relation to the licensed IP unless prior approved by the CP.

Issue 5*: The RO researcher incentives are often not aligned closely with those of the CP.*

Consideration should be given to providing an option for key RO researchers to receive equity in the licensed project to align the incentives of the researchers with those of the CP/investors.

Other comments

To encourage "home grown" commercialisation success stories, consideration should be given as to whether the HERC framework guidelines and standard documentation should provide more favourable commercialisation terms for CPs that are small Australian companies or entrepreneurs, as opposed to the terms offered to large multi-national and foreign corporations. Ideally the aim should be to create more value locally (through the creation of local jobs, local companies, local expertise, increasing asset value, opportunities for local investment, additional Australian origin IP, etc.,) to foster the development of thriving local biotech clusters in Australia.

To further incentivise commercialisation of IP at ROs, adoption and publication of metrics on the number of RO licensing deals to local CPs over time, time to licensing post patent, and number of unlicensed patented assets should occur. This will increase competition, transparency and accountability across ROs.