Consortium for Medical Deveice Technologies

IP Management Plan

Definitions

"Project" – a body of work that will be undertaken collaboratively amongst the CMDT partners for a third party including government and industry.

"Project Team" – A team of researchers from the CMDT partners that have been identified to work jointly on a "Project".

"Project Leader" – Person that has been allocated the responsibility of leading the "Project" and "Project Team" by the CMDT Steering Committee

"Science Leader" – Principal Investigator(s) in a "Project"

"Project Management Group" – A Group formed to oversee the "Project" comprising a Science Leader from each organisation involved and led by the 'Project Leader"

A. Collaborative Research

1. Introduction

Project collaboration between Callaghan Innovation, University of Auckland (UoA), Auckland University of Technology (AUT), University of Canterbury (UoC) and University of Otago (UoO), is governed by a Memorandum of Understanding as part of the Consortium for Medical Device Technologies (CMDT).

All five organisations have current policies and procedures in place which direct the management of their intellectual property (IP) assets. The IP management processes are designed to ensure that all valuable or potentially valuable IP is well protected both for the benefit of the organisation and for New Zealand.

This IP Strategy document provides the foundation for the management of IP generated in collaborative work and is consistent with and supportive of business strategies, commercialisation and technology transfer plans and science strategies within the organisations. IP and commercialisation decision making is guided principally by commercial imperatives in the context of a portfolio of technology investment opportunities. This is in line with the CMDT vision of creating value for New Zealand with and through its industry partners.

The value to New Zealand will be created through making new IP available to New Zealand companies who are already operating and may already be trading in appropriate international markets, as well as through the creation of new start-up companies. New IP will add significant value to the individual companies' product portfolios and allow the development of new products

and systems that will have international appeal in a growing medical device market environment. Additionally, the CMDT is also keen to support the establishment of spin-out ventures from the various founding organisations through its IP where relevant, thus growing the medical device sector through new ventures.

2. Process

- Each joint CMDT project will be supported by a Project Management Group (PMG) comprising the Project Leader and Science Leads from the various organisations involved in the project. Part of the PMG's duties will be to decide, with suitable expert advice, if and when it is timely and desirable to protect new Project IP. It will also decide which partner will be responsible for IP protection including the filing of specific patent applications. Partner institutions will provide a Business Lead representative to attend the PMG meetings when matters arise regarding IP associated with their work.

- New Project IP identification will be the responsibility of the Project Leader in consultation with the joint CMDT project team and the PMG. Particular consideration is to be given to milestone finish dates and to promised Specific Outputs where these involve patenting or other IP protection measures.

- On a case by case basis, the PMG, in consultation with the project team, will determine relative contributions made by each partner to any Project IP taking into account both inventive and cost contributions. Each invention contribution ratio determined by the PMG will be formalised by contractual agreement and the ratio subsequently used to determine ongoing cost sharing, future value sharing as well as commercialisation leadership. Previously agreed dispute resolution measures will operate should the PMG be unable to reach agreement on any question.

3. Decision to Patent Valuable IP – IP Strategy

(i) A decision to patent new Project IP will be taken by the PMG with input from the constituent organisations according to their own internal processes.

(ii) Records will be kept of all IP decision making processes.

(iii) IP management decisions will be informed by the results of "patentability" and "freedom to operate" patent searches as appropriate in order to minimise commercial risk and maximise commercial value of the IP.

(iv) If new Project IP is to be shared with another contracting partner outside the CMDT then decisions in (i) and (iii) above may be made jointly with that partner subject to the terms of the relevant contract. Any agreements with partners outside of the CMDT founding partners should be tabled when a project is initiated.

(v) The IP strategy will, wherever possible, take an IP portfolio approach meaning that individual patenting decisions will be made in the context of the enhanced potential for value creation from a coherent portfolio of related patents.

4. PROJECT IP DETAILS

- Existing IP Landscape

A literature and patent search will be undertaken prior to the project commencing to understand the existing IP landscape. The Project Leader will be responsible for ensuring that this is completed and recorded. A summary of existing IP and ownership will be attached to the Project Letter of Agreement required for joint projects under the CMDT Memorandum of Understanding conditions.

- Background IP

Any existing know-how and IP that is brought to the start of a project by the CMDT partners involved remains the property of the individual organisations. This will be recorded by the Project Leader and appended as a schedule to the Project Letter of Agreement which is required for joint projects under the CMDT Memorandum of Understanding conditions.

- Routes to value creation from this new IP

It is intended that an agreed lead organisation will be primarily responsible for formal IP protection measures and subsequent commercialisation (or any other means of extracting value for New Zealand) and will have agreed decision-making authority. However, that party will be obliged to consult and consider representations from any other party that has beneficial rights derived from that particular project IP generated. Project IP managed by one party but required by another for a separate commercialisation project may be cross-licensed where appropriate.

The commercialisation leader will be responsible for obtaining any regulatory clearances, such as approval to undertake clinical testing, required to progress any commercialisation objectives, but other collaborating parties will provide support as required.

As an integral part of any commercialisation, regular literature and patent update searches of the prior art will be undertaken and a formal freedom to operate clearance sought from a qualified patent attorney prior to significant investment in a new commercial venture.

B. Fee for Service Projects

IP arrangements will be agreed with the industry partner or partners involved prior to the commencement of a project.

A lead negotiator from the CMDT organisations involved will be appointed to work with the industry partner on behalf of the joint project team. Any agreements presented to the industry partner will have been discussed and endorsed by the organisations involved.

The principles in Part A will apply except where they contradict industry partner requirements.