Boosting the Commercial Returns from Research

28 November 2014

MTAA response to discussion paper

Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (+612) 9900 0650
F (+612) 9900 0655
E reception@mtaa.org.au

INTRODUCTION

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small and medium sized Australian innovator companies.

Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, to diagnostic imaging and operating theatre equipment, to products which incorporate biological materials or nanomaterials. The industry is characterised by a high level of innovation, resulting in short life cycles for many products. Medical technology innovation is characteristically incremental in nature. Many medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical technology.

The Australian medical technology industry[1]:

- had turnover of approximately $10.2 billion in 2012-13 (revenue is ~$11.8 billion if *in vitro* diagnostic (IVD) and dental products are included)
- included over 500 medical technology companies with products listed in the ARTG
- was responsible for ~44,000 medical devices listed on the 2014 ARTG, estimated to represent between 500,000 and one million different devices
- employed more than 19,000 people
- was mainly located in NSW (55%) followed by Victoria (24%) and Queensland (12%)
- imported goods to the value of $4.4 billion and exported goods to the value of $1.9 billion in 2013.

The medical technology industry compares favourably in turnover and size with other major Australian industries. The automotive manufacturing industry had revenue of $11 billion in the period 2011-12, with employment at around 16,289, while the wine industry had revenue of $7 billion and employment of 13,208 in the same period. In 2011–12, health spending in Australia was estimated to be $140.2 billion. Australian demand for medical technology is growing due to the ageing population and increased prevalence of chronic diseases.

The medical technology industry is a sector that invests heavily in research and development (R&D). It has been estimated that high technology medical technology companies in the US devote upwards of 20% of their revenue to R&D.[2] In Australia, the annual spend for R&D in 2011-12 for medical and surgical equipment manufacturing was $237 million, which was an

[1] Medical Technology in Australia: Key facts and figures 2013, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2013)
[2] USITC 'Medical Devices and Equipment: Competitive Conditions Affecting US Trade in Japan and other principal foreign markets', March 2007

increase of approximately $20 million (9%) from the previous year.[3] Patent applications by medical technology companies provide a good indicator of innovation, and the number of Australian medical technology patent grants has shown a steady increase since 2009.[4] These data are favourable and suggest that there is a strong culture of innovation in Australia.

BOOSTING THE COMMERCIAL RETURNS FROM RESEARCH

The Australian Government, as part of its 'Industry Innovation and Competitiveness Agenda', will develop and implement a strategy to improve Australia's economic performance through better translation of research into commercial outcomes. The MTAA welcomes the opportunity to respond to the discussion paper, and this submission addresses a number of strategies that can be employed in order to boost the commercial returns from research in Australia.

Adjusting research funding mechanisms to provide greater incentives for collaboration between research and industry

There is agreement within the research community that the current competitive public funding schemes for research in Australia, such as those administered by the ARC and NHMRC, do not encourage collaboration between the public and private sectors.[5] Therefore, there is a need for alternative funding schemes focused specifically on fostering collaboration between research organisations and industry.

One such initiative is the Medical Device Fund, established by the NSW Government as a $5 million per annum, competitive technology development and commercialisation program.[6] In its inaugural year (2012-13) $10.3 million was committed to a total of five projects. In 2014-15, $7.7 million will be made available. The Fund's objectives are to promote new and innovative medical devices/technologies within NSW that may have global benefit. In addition the scheme aims to provide support for research groups, hospitals, industry, individuals and companies to take local innovation to market as well as to increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes.

Another program which supports early stage commercialisation through the provision of specific skills and advice is the Medical Device Partnering Program (MDPP) at Flinders University in South Australia, which has received funding from the South Australian government.[7] This program facilitates collaboration between researchers, companies, end-users and government and is focused on developing cutting-edge medical devices and assistive technologies and bringing them to market.

The medical technology sector is considered high risk compared with other industry sectors, and the return on investment is typically long-term. Each stage in the development of a MedTech product can be lengthy (albeit significantly shorter than pharmaceutical development) and it is commonly accepted that it can take between 5–10 years to get a product to market. Access to funding is one of the greatest challenges, particularly for small

[3] ABS 81040D009_201112 Research and Experimental Development, Businesses, Australia, 2011-12
[4] WIPO Intellectual Property Statistics Data Center. Available at: http://ipstats.wipo.int/ipstatv2/
[5] Advisory Council on Intellectual Property 2012, *Collaborations between the public and private sectors: The role of intellectual property*, Final report, Canberra.
[6] NSW Medical Devices Fund 2014 – 2015. Available at: http://www.health.nsw.gov.au/ohmr/mdf/pages/default.aspx
[7] Medical Devices Partnering Program. Available at: http://www.flinders.edu.au/mdpp/mdpp_home.cfm

to medium enterprises (SMEs), which make up over 70% of the Australian medical technology industry. It is important that the financial contributions expected from SMEs (in collaborations with research institutions) should be proportional to their annual turnover, rather than a fixed amount. Programs such as the ones outlined above provide critical assistance in the early stages of developing a product to take it to market. In order to achieve long-term, consistent translational research benefits, these programs need to be available on an ongoing basis from state and territory governments or from the Federal Government in the form of Commercialisation Australia grants which are critical for the industry and which have provided significant benefit to date.

Supporting the provision and maintenance of world-class research infrastructure to attract the world's best researchers and facilitate collaboration with industry

One mechanism for supporting more effective translation of research is the *development of innovation hubs* which bring together research bodies and industry. The importance of achieving competitive advantage through collaboration and clustering has been recognised by the Australian government in its innovation white paper, 'Powering Ideas: An Innovation Agenda for the 21st Century'.[8]

While there are no outstanding examples of effective innovation hubs in Australia, a hearing hub has been developed at Macquarie Park in Sydney (within the Global Technology Corridor) based around the Cochlear facility, the medical device company responsible for development of the cochlear implant.[9] The physical infrastructure for this cluster is in place. What is missing from this vibrant business and research hub is the social and commercialisation infrastructure to make it internationally competitive. Social infrastructure is the critical component of diffusion of knowledge amongst relevant parties. Commercialisation infrastructure is the mechanism to highlight the potential of research projects at the early stages ensuring the right linkages are in place to get the product to market.

A study undertaken in Sydney in 2010 led by Professor Roy Green examined the potential for industry clusters to deliver significant competitive advantage for regions with a concentration of innovative and entrepreneurial activity.[10] This study focused on the ICT and bio-medical industries in the Global Technology Corridor in Northern Sydney. The report found that while businesses in the biomedical sector are co-located in the Global Technology Corridor, there is a low level of collaboration and knowledge diffusion among the companies.

The MTAA is currently working with the NSW Government to establish a MedTech Knowledge Hub focused on improving collaboration between academia, industry, government, venture capital and the health system. The Hub's focus will be on:

- developing policy and program ideas that establish a supportive business environment for all facets of the industry – manufacturers, distributors and importers of medical devices
- accelerating the translation of Australia's research investments into commercial products to be adopted in our health system and overseas by addressing the local challenges that prevent commercialisation opportunities

[8] *Powering Ideas: An Innovation Agenda for the 21st Century*, Commonwealth Government, December 2009

[9] Australian Hearing Hub. Available at: http://hearinghub.edu.au/

[10] Macquarie Graduate School of Management, University of Technology Sydney and Bugseye Pty Ltd, in collaboration with Industry and Investment NSW and the Australian Business Foundation 'Northern Sydney's Global Technology Corridor: A Scoping Study of Cluster Development' Sydney, 2010

- acting as the vehicle to coordinate all industry partners to work together more strategically to realise the industry's potential.

There is strong international evidence to show that effective clustering can result in significant development of entrepreneurial activity, and there are several examples of successful medical technology industry clustering in other countries around the world.

Singapore has supported the development of the Asia Pacific's best known industry cluster, the Biopolis. Part of its offering includes strong intellectual property protection and enforcement and free trade agreements. It is located close to the National University of Singapore, the National University Hospital and the Singapore Science Parks. It describes itself as 'dedicated to biomedical R&D activities' and boasts 'an environment that fosters a collaborative culture among the private and public research communities'.

The Medicon Valley, which spans eastern Denmark and south-western Sweden, is one of the top three life sciences clusters in Europe, and employs more than 40,000 people.[11] There are 164 medtech companies, 111 biotech, pharmaceutical and contract research companies, and 12 universities, in the Medicon Valley. The body behind Medicon Valley is the Medicon Valley Alliance, a non-profit organisation which works to create new research and business opportunities in the region. It also works with its members to improve their innovation skills and competitiveness, and acts as a point of entry for foreign stakeholders.

Tax incentives are vital for innovation. The *R&D Tax Incentive* was introduced in 2011, replacing the R&D Tax Concession, R&D Tax Offset, and the associated Incremental Premium and International Premium Concession systems. It provides a tax offset to encourage companies to engage in R&D and product development. The R&D Tax Incentive provides a 43.5% refundable tax offset to eligible entities with an aggregated turnover of less than $20 million per annum and a non-refundable 38.5% tax offset to all other eligible entities. The incentive helps businesses offset some of their R&D costs. It is a broad-based entitlement program open to companies of all sizes in all sectors that are conducting eligible R&D. It is important that the Australian Government continues to support the R&D Tax Incentive.

Increasing labour mobility within the research sector is another way of facilitating greater collaboration between research institutions and industry. In Australia, there is a need for policies at the governmental and institutional level, which focus on redesigning academic careers in order to encourage mobility. Specifically, policies are needed which reduce existing barriers to mobility, and enable academic researchers to move in and out of academia without major penalties.[12] One well known international initiative is the Marie Skłodowska-Curie actions - Research Fellowship Programme (MSCA), which focuses on international mobility, as well as on mobility between academic organisations and industry.[13] The MSCA supports a variety of research endeavours, including 'blue-sky' science, industrial doctorates, as well as combining academic research with work in industry.

[11] Medicon Valley Alliance. Available at: http://www.mva.org/
[12] University – Business Collaborative Research: Goals, Outcomes, and New Assessment Tools – The EUIMA Collaborative Research Project Report, European University Association, 2014
[13] Marie Skłodowska-Curie actions - Research Fellowship Programme. Available at: http://ec.europa.eu/research/mariecurieactions/

Promoting intellectual property arrangements that facilitate, rather than frustrate, collaboration and commercialisation of ideas

It is widely acknowledged that in order to encourage innovation and ensure Australia's competitiveness, a robust and globally consistent intellectual property (IP) system is essential.

The MTAA is part of a group of organisations, including Cook Medical Australia, AusBiotech, and the Export Council of Australia, that has proposed an Australian Innovation and Manufacturing (AIM) Incentive, or 'Patent Box' scheme focused on supporting local innovators and manufacturers.[14] Specifically, the scheme would offer a reduction in tax payable from profits derived from the commercialisation of qualifying IP, which would address the current gap which leaves Australian IP vulnerable to being sold or manufactured overseas. Once an innovative idea reaches the commercialisation phase, companies would be incentivised to keep Australian IP and manufacturing in Australia (the scheme would reward companies who succeed in exporting products).

The 2013 'Strategic Review of Health and Medical Research' identified a need to strengthen Australia's IP system, reporting that while a large number of patents are filed by Australian researchers, many of these patents are not commercially viable.[15] This review recommended that one of the ways of enhancing the commercialisation environment in Australia would be to encourage researchers to ensure that their IP has been properly assessed for its potential commercial value before filing patents.

Research Australia has suggested that alternative models for sharing IP are required in order to improve engagement between academia and industry.[16] One example of this is the EasyAccess IP initiative, which makes available free-of-charge to industry partners IP that research institutions do not intend to commercialise, facilitating collaboration between the public and private sectors.

A 2012 study by the Advisory Council on Intellectual Property (ACIP) investigated how IP acts an enabler or disabler of knowledge sharing, translational research and collaborations between Australian publicly-funded research organisations (PFROs) and industry.[17] This review found that in most cases, IP plays an important role in collaborations. In ACIP consultations, industry stakeholders reported that with regard to IP identification and management, PFROs could be more sophisticated in their dealings with industry. Similarly, some PFRO stakeholders felt that their interactions with industry could be aided by having greater clarity and consistency in applying internal IP identification and management. One of the recommendations of this review was that the development and promotion of educational resources (supported by relevant training) to assist PFROs, industry and researchers to form and conduct collaborations, should be encouraged. This included the possible development of a module focusing on background IP (contributed to a collaboration) and project IP (arising from collaborations), including the proper identification and management of both.

[14] MTAA submission to 'Senate Economics Reference Committee – Inquiry into Australia's Innovation System', August 2014

[15] *Strategic Review of Health and Medical Research in Australia – Better Health Through Research*, Commonwealth Government, April 2013

[16] Research Australia submission to consultation paper on 'Science, Research and Industry Innovation Strategy for South Australia', January 2013

[17] Advisory Council on Intellectual Property 2012, *Collaborations between the public and private sectors: The role of intellectual property*, Final report, Canberra.

Ensuring research training prepares researchers to work with industry and bring their ideas to market

In Australia research has traditionally been conducted in the university sector. Approximately 60% of all Australian researchers are employed in higher education, with another 10% employed in research agencies. Only 30% of Australian researchers are employed in the private sector, in contrast with 80% in the US, 64% in Switzerland and 70% in Japan.[18]

A well documented issue in Australia is the lack of entrepreneurial skills in researchers/innovators. Current research training does not provide relevant industry-specific professional skills to students to allow them to 'hit the ground running' in an industry context following the completion of their studies. In particular, many researchers lack an understanding of the full innovation and product development pathway, including aspects which ideally should be factored in at the research project planning phase, such as customer-focused design, regulatory hurdles, project management, manufacturability issues and scope for IP protection. It is also important that the ability of researchers to work with international teams to solve issues of global significance is nurtured. Therefore, there is a need for initiatives which enable researchers to develop the skills and experience necessary to equip them for collaborative research opportunities with industry partners, or positions within the private sector.

The US National Science Foundation in collaboration with the US National Health Institute (NHI) have developed an initiative which equips scientists with business training to help them transition from skills required in academia to skills required in the business world.[19] The goal is to accelerate the development and commercialisation of drugs, devices and services. The Innovation Corps at NHI or I-Corps accepts applications from recipients of specific grants (SBIR and STTR) and a nine week boot camp educates biomedical entrepreneurs on business matters such as how their companies can protect intellectual property and develop regulatory and reimbursement strategies.

The 'SPARK Program' at Stanford University in the US, is another initiative focused on educating researchers on the discovery and development process.[20] Specifically, the program was created as an innovative, cost-effective way to overcome the hurdle associated with translating academic discoveries into drugs or diagnostics that address real clinical needs. Such obstacles include the need for unique—and costly—dedicated core facilities and services, the specialized knowledge required for drug discovery and development, and the funding gap for projects in the applied research phase (between basic science discovery and clinical application). SPARK provides access to specialised knowledge and technical expertise regarding drug and diagnostic development, dedicated core laboratory facilities, and sources of funding to support translational efforts. This initiative provides a cost-effective model to generate proof of concept, using industry standards, and to date, of the 51 projects that have completed the program, 57% have been licensed to funded companies and/or entered clinical testing.

A similar program has now been established in Sydney. 'SPARK Sydney' is jointly hosted by the University of Technology Sydney (UTS) and the Kolling Institute (Northern Sydney Local Health District).[21] The program is focused on building relationships between the two institutions, government and the pharmaceutical industry within Sydney and internationally.

[18] Science, Technology, Engineering and Mathematics in the National Interest: A Strategic Approach, Office of the Chief Scientist, July 2013
[19] National Science Foundation. Available at: http://nsf.gov/news/news_summ.jsp?cntn_id=131760
[20] SPARK – Stanford University School of Medicine. Available at: http://sparkmed.stanford.edu/
[21] SPARK Sydney – University of Technology, Sydney. Available at: http://www.uts.edu.au/about/faculty-science/what-we-do/partnerships-and-collaborations/spark-sydney

Specifically, this program offers research staff at both institutions mentorship and seed funding for translational research in therapeutics, diagnostics and medical devices. For winning projects, up to $40,000 per annum in funding is provided (for up to two years) to run the proof of concept stage.

The NSW Medical Device Commercialisation Training program is designed to provide researchers with commercialisation skills.[22] It is available to post-doctoral and other researchers who have an interest in the development of medical devices. The three month intensive training program fulfils a commitment to build medical device commercialisation capacity in NSW. It contributes to the discovery and application of new treatments and diagnostic techniques to improve patient outcomes.

Improving assessment of the research system, including measuring and publishing collaboration and commercialisation outcomes, as well as research outcomes and impact

There is an increasing awareness of the need to broaden the criteria used to assess research performance in PFROs. The assessment of research performance is still dominated by a focus on indicators such as:

- manuscripts published in high-impact peer-reviewed journals
- research student (Masters and PhD) enrolments and completions
- success in securing competitive public research grants (ARC and NHMRC)

The recent ACIP review found that both PFRO and industry stakeholders were strongly in agreement that current performance metrics for PFROs do not provide a strong incentive for the formation of collaborations with industry partners.[23] Specifically, the key performance indicators (KPIs) for PFROs are linked either directly or indirectly to funding, which in turn drives the behaviour and allocation of resources in these institutions. During ACIP consultations, researchers from PFROs raised concerns that the reward structure did not encourage them to participate in collaborations with industry. In particular, early career academics felt that they needed to focus on publishing their research and securing ARC and NHMRC grant funding, activities that had the most significant impact on their career advancement.

Therefore, in addition to the traditional indicators already in use, there is a need for indicators which focus on the outcomes of the collaborative research process between academia and industry, including:

- peer-reviewed manuscripts co-authored with industry partners
- collaborative, contract and consultancy research projects completed
- number and survival of spinoffs
- number of patents and license agreements
- research students who have completed industry placements/training
- research students employed in industry following graduation

Recently, a new assessment tool has been developed by the EUIMA project, which includes a range of outcomes of collaborative research that universities and their industry partners

[22] http://www.health.nsw.gov.au/ohmr/Pages/nsw-medical-device-tp.aspx
[23] Advisory Council on Intellectual Property 2012, *Collaborations between the public and private sectors: The role of intellectual property*, Final report, Canberra.

can consider when designing and assessing collaborative research projects.[24] This tool includes indicators reflecting:

- different forms of collaboration
- different qualitative or semi-quantitative outcomes of the partnership
- long-term effects of university business partnerships in the institutions/organisations themselves and in their environment

CONCLUSION

The MTAA believes the Federal Government could work more strategically with innovative industries such as the medical technology sector to identify measures to improve the translation of research into innovative products for the healthcare market, ensuring that Australia captures the full economic value from its research, which in turn will contribute to national prosperity. The MTAA argues that these measures should include:

- Introduction of ongoing funding opportunities focused specifically on fostering collaboration between research organisations and industry (in particular SMEs)
- Introduction of innovation hubs/clustering among research organisations and industry, to mitigate the issues which are currently obstacles to commercialisation in Australia
- Continued support of the R&D Tax Incentive
- Introduction of an Australian Innovation and Manufacturing (AIM) tax incentive scheme that supports developing and maintaining IP in Australia
- Providing researchers with relevant training on industry-specific professional skills, covering areas such as customer-focused design, regulatory hurdles, manufacturability issues and scope for IP protection
- Broadening the criteria currently used to assess research performance, to include indicators which focus on the outcomes of the collaborative research process between academia and industry, such as the number of patents and license agreements, number and survival of spinoffs, and research students who have completed industry placements/training

[24] *University – Business Collaborative Research: Goals, Outcomes, and New Assessment Tools – The EUIMA Collaborative Research Project Report*, European University Association, 2014