Boosting the commercial returns from research

A CSL submission to the Department of Education and the Department of Industry

12 December 2014

CSL™

Summary of comments and recommendations

CSL develops, manufactures, and markets pharmaceutical products of biological origin to treat and prevent serious human medical conditions. CSL is Australia's largest biotechnology company and a global leader in plasma-derived therapies, their recombinant analogues, and influenza vaccines. CSL is an Australian 'innovation-active business', to use the language of the Department of Education and Department of Industry issues paper 'Boosting the commercial returns from research'.

The CSL Group has a global footprint, with the majority of its sales outside Australia. Nevertheless, CSL is headquartered in Australia and maintains a substantial research and development ('R&D') presence in Melbourne, Australia. CSL has a successful track record in the development of innovative medicines for global markets, and maintains and develops a pipeline of prospective products in various stages of development that may in turn become life-saving medicines for sale into global markets. In addition to its substantial expenditure on R&D, CSL continues to invest in infrastructure, in Australia and elsewhere, to support that R&D, and manufacturing facilities necessary to support commercial sales into global markets.

We welcome the opportunity to make a submission to the Departments of Education and Industry on this important issue. CSL has made a number of other public submissions addressing these and related issues, two of which, our 2012 submission to the McKeon Review and our 2014 submission to the Senate Inquiry on Australia's Innovation System, are attached to this submission. CSL makes the following observations and recommendations concerning boosting the commercial returns from Australia's public research.

Australia would benefit from increased government support for research, particularly directed at increased translational research.

CSL's view is that Australia is seeking (and should seek) to establish an education and basic research environment that is towards the top end of the OECD spectrum. Australia is an attractive location for research. It has, for example, high quality universities and institutes, a good supply of skilled researchers and English as its language. At present, Australia broadly speaking sits somewhere close to the average in respect of the proportion of its GDP spent on R&D, at 2.21%. In CSL's view, increased support for research, appropriately directed, would be likely to result in a more than commensurate increase in commercial development.

The basic research from universities and research institutes provide an essential input to the medical and biopharmaceutical sector in which CSL operates. Accordingly, CSL would welcome further government support for university science and technology and the research institutes in order to increase the supply of these essential cornerstones to the sector (knowledge spillovers and IP that can be developed into commercial products). These institutions also help train and develop a pool of highly skilled scientists and researchers entering the work force; further funding therefore helps increase the size of the skills base on which CSL and the innovation economy more generally rely.

CSL welcomes the Medical Research Future Fund ('MRFF') which has the potential to substantially enhance the commercial returns that Australia earns from its investment in medical sciences. The fund is expected to double the Government's direct contributions to medical research by 2020 as a means of providing further and sustainable support for basic and, particularly, translational research in biological, pharmaceutical and medical science.

In CSL's view, greater government support for translational research, in particular, would increase the pool of high quality projects available for further development and commercialisation, and this would, in turn, boost the commercial returns from Australian research. CSL has previously recommended new government funded Translational Grants to replace NHRMC Development Grants to fulfil this role. These grants should be dependent upon partnerships and collaboration between the research institution, credible industry partners, and the primary health and hospital sectors.

Current support for business R&D strikes an appropriate balance.

The 45% refundable R&D tax offset for smaller firms and the 40 per cent non-refundable tax offset to larger firms represent an appropriate level of support, and strike an appropriate balance between overly proscriptive definitions of R&D, and the risk of supporting R&D that would take place anyway, without the support. However, for Australian shareholders of Australian listed businesses that are profitable, the value of support for R&D through the tax system is reduced by Australia's system of imputation credits.

CSL concurs with the Pharmaceutical Industry Strategy Group ('PISG') that direct government support in the form of co-investment or support for specific investments can in some circumstances be an appropriate means of delivering enhanced commercial benefits from Australian research, particularly where it more firmly embeds Australia into global manufacturing supply chains and strengthens Australia's technology clusters. CSL has benefitted from direct support from the Commonwealth and Victorian governments for investments that have done this.

Australia is not an attractive place from where to commercialise products from its research.

The Issues Paper has identified a number of factors that impede commercial development of Australian research that might be termed 'supply' constraints. These include, for example, the lack of 'hubs' such as the Cambridge Science Park, lack of intermediaries to facilitate integration of universities and business; lack of incentives to encourage entrepreneurship, too high a proportion of scientists working in academia rather than business, and lack of funding. CSL concurs with many of the observations the *Issues Paper* makes in this regard.

However, in CSL's view, there is a more fundamental problem commercialising Australia's research which is demand rather than supply driven. Most businesses wanting to serve global markets would not choose to complete the development, and then manufacture of innovative products, from Australia. There is very little demand by global businesses to undertake late-stage development, commercialisation and manufacture of high value-added products from Australia.

A number of fundamental factors discourage businesses from completing the product development process in Australia. These include the size and location of the Australian market relative to global markets, relatively high labour costs and, most particularly, high corporate tax rates compared to peer jurisdictions. These impediments strongly discourage firms from placing high value manufacturing ('footloose investment') in Australia.

As a result, Australia does not reap full value from the IP it generates from its research base including the benefits of investment in manufacturing, the increase in skilled employment and the wages they earn, the acquisition of skills in related areas such as compliance with US and EU pharmaceutical regulation, and multiplier effects. There are also other intangible benefits from manufacturing and commercialisation, such as follow-on R&D in related areas, the emergence of new or related products, and clustering effects where other manufacturers are attracted by the availability of resources and skills.

CSL considers that the most effective policy for commercialising Australia's research is to make Australia, through the tax system, an attractive location for businesses doing late-stage development and commercial manufacture of high value added products for global markets.

High corporate tax rates can be a significant impediment to new investments in late-stage development and commercial manufacture. In this regard, it is notable that Australia's corporate tax rate is high by OECD standards, and Australia is one of the few countries that has not reduced its corporate tax rate since 2005.

Australia's corporate tax rate is considerably higher than many of its peers. For example, that the UK is progressively reducing its corporate tax rate to 20%, Ireland has a flat tax

rate of 12.5% and Singapore a 17% rate, and they all offer a range of further concessions related to R&D. Switzerland, where CSL has decided to locate its commercial scale recombinant coagulation factor manufacturing facility, has a range of effective tax rates for limited periods substantially below the statutory rate of around 25%, depending on canton and commune.

Where multiple countries with a similarly favourable investment climate are competing to attract direct investment, tax competition can play a critical role for footloose firms deciding whether to invest in a particular country or region. This echoes CSL's own experience in deciding upon the location of major new investments.

Recent initiatives in relation to the taxation of profits from IP in a number of peer economies, such as the UK, threaten to worsen Australia's position. Australia must respond.

Revenue requirements for Australian governments clearly preclude a substantial reduction in corporate tax rates, but this problem is not unique to Australia. A number of economies with strong research sectors are revising their system of corporate tax to capture the full benefits of their public research, particularly through incentives for innovation, without undermining their revenue base. The UK Patent Box, for example, allows companies to apply a lower 10% tax rate on patent derived profits provided the business made a significant contribution to the patent.

Australia should emulate these models. In order to maximise the benefits of public research to the Australian economy, including the multiplier and spillover benefits that arise from high value manufacturing in Australia, the corporate tax system must find a model that preferentially incentivises, through a sufficiently low rate, new investments in Australia when the investment is genuinely footloose, derived from IP developed to a significant degree in Australia, that results in the late-stage development, commercialisation and manufacture from Australia.

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Introduction

CSL develops, manufactures, and markets pharmaceutical products of biological origin to treat and prevent serious human medical conditions. CSL is Australia's largest biotechnology company and a global leader in plasma-derived therapies, their recombinant analogues, and influenza vaccines.

CSL is an Australian 'innovation-active business', to use the language of the Department of Education and Department of Industry issues paper 'Boosting the commercial returns from research' ('*Issues Paper*'), published in support of the business-focused elements of the Commonwealth Government's Economic Action Strategy. This is apparent from CSL's structure and performance.

The CSL Group has a global footprint, with the majority of its sales outsider Australia. Nevertheless, CSL is headquartered in Australia and maintains a substantial research and development ('R&D') presence in Melbourne, Australia. CSL is also developing new manufacturing facilities in Melbourne to serve those global markets. CSL has a successful track record in the development of innovative medicines for global markets. CSL was instrumental in the development of Gardasil®, helping translate research from the University of Queensland into a valuable global vaccine. CSL maintains and develops a pipeline of prospective products in various stages of development that may in turn become life-saving medicines for sale into global markets (see Figure 1).

CSL therefore has considerable experience of creating commercial returns from research that has its origins in, or has largely been undertaken in, Australia. In doing this, we have created substantial value for our shareholders and, in addition, large benefits to the Australian economy. These include knowledge spillovers from our R&D, skilled employment in R&D and advanced manufacturing, and production, investment and employment in a broad range of supporting businesses through the multiplier effects of our Australian operations.

CSL believes that its knowledge and experience can be helpful in shaping Government policy that will further boost the commercial returns from Australia's high quality research base. Accordingly, we welcome the opportunity to make a submission to the Departments of Education and Industry on this important issue. CSL has made a number of other public submissions addressing these and related issues[1] two of which, our 2012 submission to the McKeon Review and our 2014 submission to the Senate Inquiry on Australia's Innovation System, we attach to this submission.

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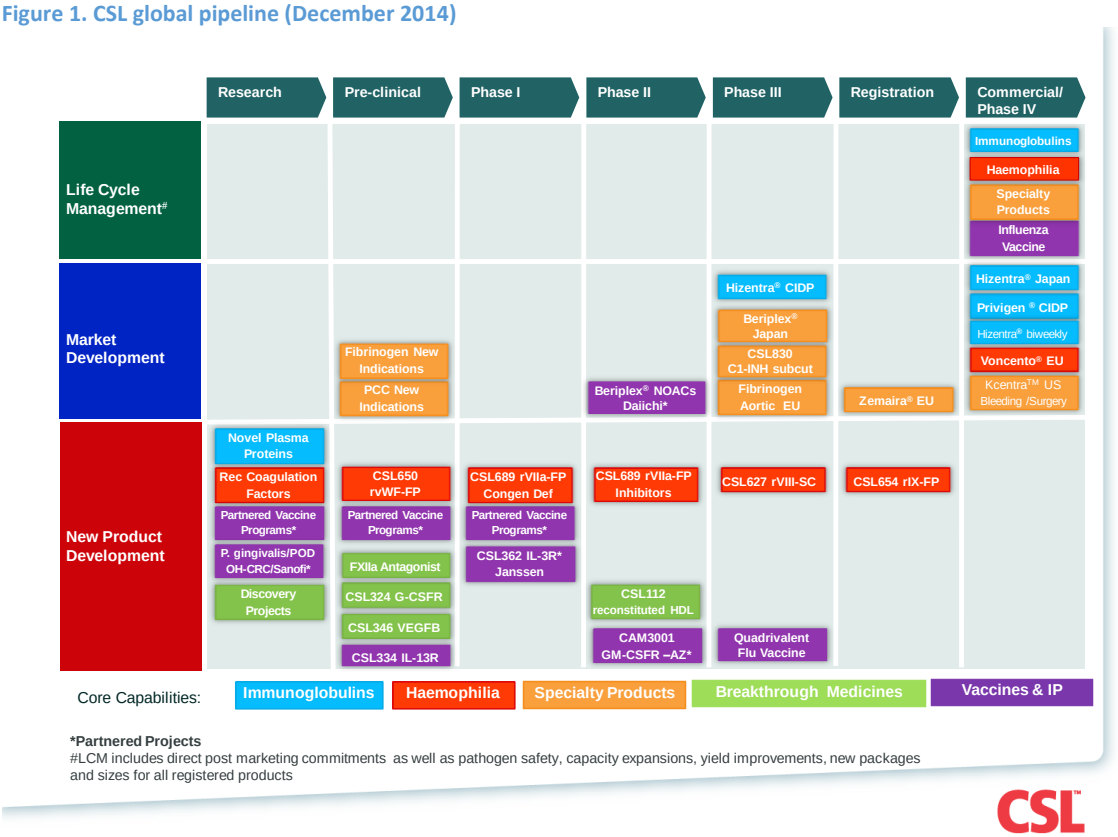
[1] See for example CSL (December 2006) *Submission to the Productivity Commission Research Study into Public Support for Science and Innovation in Australia*; CSL (April 2008) *Submission to the Review of the National Innovation System*; CSL (September 2008) *Response to the Review of the National Innovation System*, CSL (September 2009) *Response to Treasury's Consultation Paper "The new research and development tax incentive,"* CSL (March 2012) *Submission to the McKeon Strategic Review of Health and Medical Research* and CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System*.

Figure 1. CSL global pipeline (December 2014)



In this submission, we first provide a brief summary of CSL's history, operations and R&D. We then summarise what we consider to be the most important factors that drive commercial returns from research, referring where appropriate to these earlier submissions. Finally, we highlight policy steps that, in CSL's experience, can be expected to boost the commercial returns that businesses in Australia can earn from research.

1. CSL's research, development and commercialisation activities

CSL was established in 1916 to provide the Australian community with human vaccines and sera that could not be guaranteed in the event of war. CSL continues that proud tradition, supplying products of national interest such as seasonal influenza vaccine, pandemic influenza vaccine, plasma products made from Australian plasma, antivenoms and other vaccines.

CSL was incorporated in 1991 and sold by the Commonwealth Government in 1994. CSL's evolution into a global speciality biopharmaceutical company involved the acquisition of the Swiss Red Cross fractionator ZLB (2000), US blood collection centres from NABI (2001) and Aventis Behring (2004). Since then, CSL has consolidated its position as a leader in the global market for plasma-derived medicines and as an innovator in these products, vaccines, and recombinant proteins. Throughout, CSL has continued to increase its R&D expenditure, which remains a cornerstone of CSL's growth plans. CSL Limited now has a market capitalisation of

around A$37bn,[2] employs over 13,000 people globally, has major operations in 27 countries with manufacturing facilities in Europe, USA and Australia. CSL is currently Australia's 9th largest public listed company by market capitalisation.[3] In 2013/14, CSL Limited's consolidated group revenue was US$5.5bn.

1.1. CSL's R&D activities and expenditure

CSL has extensive R&D activities across all its global sites. However, CSL continues to maintain its largest R&D centre in Australia, co-located with its global corporate headquarters in Melbourne. This reflects the strategic importance of R&D and of Australia to CSL. In 2013/14, CSL's Australian operations comprised total sales of A$935 million, including $154 million in export sales; $252 million paid in wages and salaries to Australian workers; 758 million in goods and services bought from other Australian and overseas businesses; and 1,816 full-time equivalent employees.

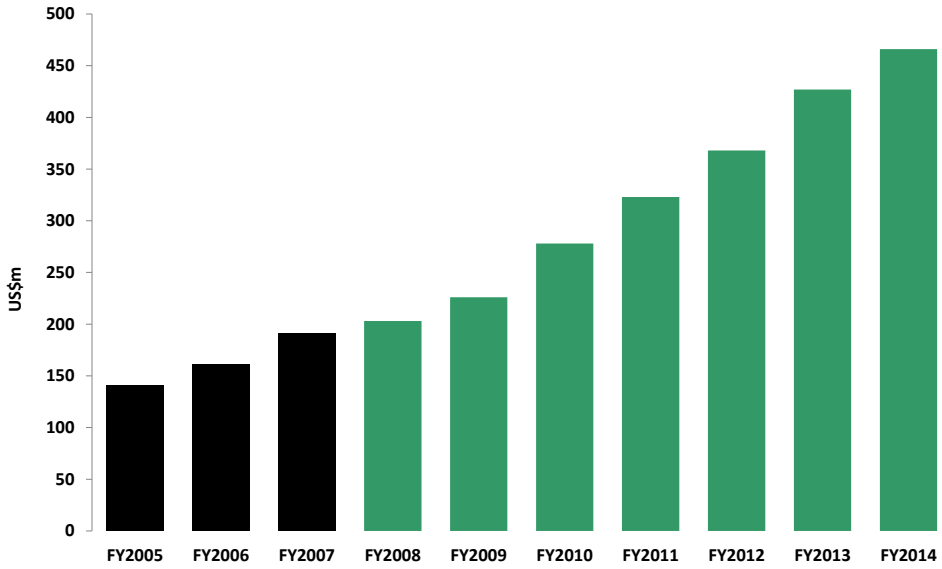
CSL's largest centre for R&D is Australia. Of the 1,816 Australian staff, more than 300 are involved in R&D, of which in excess of 80% are graduate scientists. This does not include graduate scientists and engineers working in other Australian CSL divisions. These R&D activities are based at Parkville, Broadmeadows and at CSL's laboratories at the Bio21 Institute operating on a budget of approximately $290m.

CSL has increased its R&D at a compound rate of approximately 14% per annum, from A$141m in 2004/05 to US$466m in 2013/14 (see Figure 2), and is planning further growth in the future. CSL's total R&D expenditure represents approximately 8.5% of global revenues.

Figure 2. CSL's global R&D expenditure

[2] As of 25 November 2014.

[3] ASX 25 November 2014. http://www.asx200list.com/ (last viewed 25 November 2014).



FY2005-FY2007 in AU$m. FY2008-FY2013 in US$m.

CSL has consistently ranked in the top two or three Australian companies in terms of its global R&D expenditure. By way of example, according to PwC in its 2013 Global Innovation 1000 Study[4] CSL ranked second to Telstra in its global R&D expenditure followed by Aristocrat Leisure, OneSteel/Arrium, Cochlear and Amcor; only these six firms ranked within the global top 1000. According to the 2013 EU Industrial R&D Investment Scorecard[5] CSL ranked second to Telstra amongst the Australian non-financial firms;[6] on these measures, CSL ranked 329th in the global list. These figures do not, however, detail the character of the R&D expenditure. Considerably in excess of half of CSL's R&D expenditure is on high risk potential new products.

CSL's recent investments and investment decisions

In addition to its substantial expenditure on R&D, CSL continues to invest in infrastructure, in Australia and elsewhere, to support that R&D, and manufacturing facilities necessary to support commercial sales into global markets. These include:

- the Biotechnology Manufacturing Facility located at Broadmeadows in Melbourne, opened in May 2014, to support manufacture for clinical trials and early commercialisation of its pipeline of potential new recombinant protein products;

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[4] PWC (2013) *The Global Innovation 1000: Navigating the Digital Future* http://www.strategyand.pwc.com/global/home/what-we-think/global-innovation-1000 (last viewed 16 July 2014).

[5] European Union (2013) *2013 EU Industrial R&D Investment Scoreboard* http://iri.jrc.ec.europa.eu/scoreboard13.html (last viewed 16 July 2014).

[6] The *2013 EU Industrial R&D Investment Scoreboard* (*ibid*) characterisation of Telstra and CSL expenditure on R&D is consistent with reports by other commentators. However, it places three of Australia's largest banks above CSL, indicating that it has adopted broader definition of R&D expenditure.

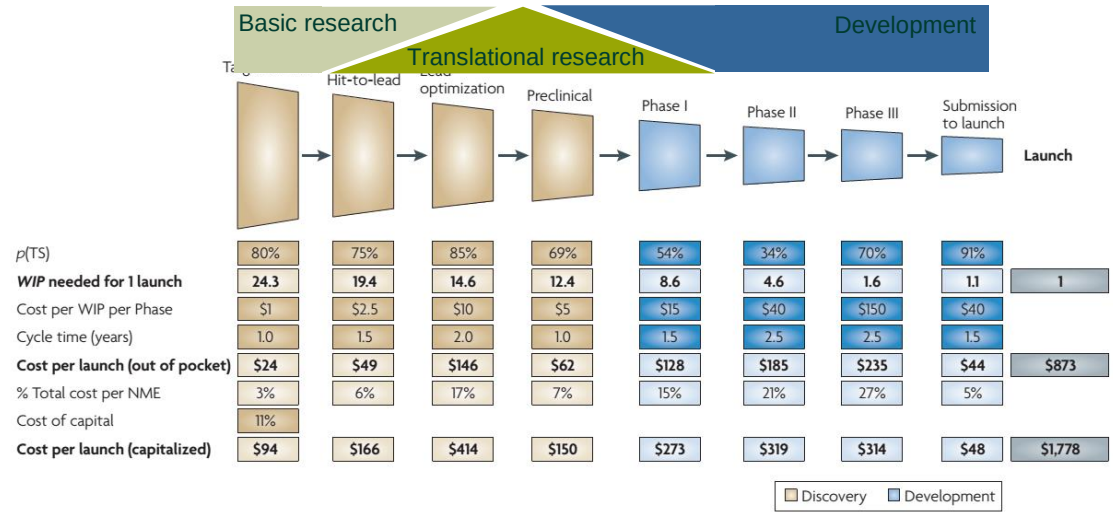
- in anticipation of growing global demand for immunoglobulins, the Privigen® toll manufacturing facility at Broadmeadows in Melbourne, currently under construction, using technology that was developed and is continually refined at CSL's facilities in Bern, Switzerland;
- in anticipation of growing global demand for albumin, an Alburex® toll manufacturing facility at Broadmeadows in Melbourne, also using Swiss technology, which will shortly commence construction; and
- a commercial scale recombinant protein manufacturing facility for CSL's pipeline of recombinant coagulation factors, which will shortly commence construction in Switzerland.

Research versus research and development

CSL notes that the title of the Departments' issues paper is 'Boosting the commercial returns from research', noting that 'Australia's research activities are conducted through universities, publicly funded research organisations, private research organisations and innovation-active businesses'.[7] CSL agrees with this, but considers that it is important to place 'research' into a proper commercial context — research *and development* — in order to identify appropriate steps for boosting commercial returns. The distinction is important.

Figure 3 illustrates the typical research and development activities (and their risks and costs) for the creation of a new drug.[8] The process is expensive (estimates range from between US$800m and US$1.7bn) and risky, with fewer than 1 in 9 candidates that enter clinical trials resulting in a product launch, fewer still becoming major commercial successes.

Figure 3. Pharmaceutical development pathway and costs



Source: Paul SM et al (March 2010) *amended by CSL*. In the stylised typical pathway, 'target to hit' represents the first stage of discovery after the identification and validation of a target for drug action, both of which are the province of basic research. It involves the identification of compounds that are active against the target. These are then refined to a lead compound ('hit to lead') which is then optimised in anticipation of preclinical development. WIP refers to 'works in progress.

Pharmaceutical R&D, for a number of reasons set out elsewhere[9] may be particularly protracted, but CSL understands that most R&D follows a broadly similar pathway that can be characterised into three basic steps (summarised at the top of the chart).

CSL has previously stated[10] that Australia, broadly speaking, sits somewhere close to the average in respect of the proportion of its GDP spent on R&D, at 2.21%.[11] CSL's view is that

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7 *Issues Paper* 3.

8 A more detailed exposition of the R&D pathway for pharmaceutical products is set out in CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System* 15-20.

9 *Ibid*.

10 CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System* 25.

Australia is seeking (and should seek) to establish an education and basic research environment that is towards the top end of the OECD spectrum. On that basis, the Commonwealth Government should assess the benefits of greater government support, which would likely move Australia up the OECD rankings.

However, in order to understand how best governments should intervene in order to increase the commercial returns from research, it is important to understand the overall process of R&D.

Basic research

Basic research is the first R&D step. It is typically not immediately directed towards a commercial product, but rather towards an understanding of the basic science that might in due course form the basis for a commercial product. Crick and Watson's work on the structure of DNA is an example of basic research. It had no immediate commercial application but provided the foundation of modern biotechnology.

Basic research is typically characterised by large knowledge spillovers[12] with the result that the benefits of the research spread far and wide and cannot be captured and retained by those that conduct the research (or the institutions in which they work). Indeed, one of the defining characteristics of research is that it is deliberately published (in academic journals) so that others can build upon it. As a result, the overall economic benefits to society from this research are typically much greater than the private benefits to the researchers or their institutions.[13]

Because there are large spillovers that cannot (and *should* not) be captured, private firms are typically unwilling to invest in basic research; they cannot capture a sufficient share of the value of the research to make it commercially worthwhile. Governments therefore play an important role in funding a sufficient level of basic research. As the *Issues Paper* notes,

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[11] OECD (2011) *OECD Science, Technology and Industry Scoreboard 2011*. The figures for Australia were from 2008. The average share of GDP spent on R&D was 2.33%. Israel, Finland, Sweden, Korea, Japan, Denmark, Switzerland, United States, Germany, Austria and Iceland were ahead of Australia in the ranking.

[12] Knowledge spillovers arise when the knowledge generated from activities is used more widely than those who create it (since most knowledge can and is freely disseminated). The acquired knowledge then generates additional and valuable economic activity.

[13] Even the semiconductor transistor, which was researched, developed and patented within Bell AT&T, an example of basic research being conducted in a business rather than academic environment, relied upon a large pre-existing body of basic research. See, for example, http://history-computer.com/ModernComputer/Basis/transistor.html and http://www.computerhistory.org/semiconductor/timeline.html.

Australia's basic research sector — primarily universities, research institutes and the CSIRO, all of which are predominantly government funded — is highly productive, internationally connected, and recognised globally for its high quality research. CSL considers that Australia is at the world forefront in a number of areas of basic research in biological sciences and human health.

In the biopharmaceutical sector, basic research often involves identifying targets such as cell surface receptors or metabolic pathways that could be possible sites for drug action, and then identifying compounds that are active against the target, of which there may be many, and which may lack specificity.

As CSL has previously stated,[14] *it welcomes further government support for university science and technology and the research institutes in order to increase the supply of these essential cornerstones to the sector: knowledge spillovers and IP that can be developed into commercial products. These institutions also help train and develop a pool of highly skilled scientists and researchers entering the work force; further funding therefore helps increase the size of the skills base on which the innovation economy relies.*

CSL welcomes the recently announced Medical Research Future Fund ('MRFF') which is expected to 'double the Government's direct contributions to medical research by 2020'[15] *as a means of providing this further support.*

Translational research

Translational research involves building on this basic research to the level of a prototype that can be tested for its suitability for commercial development. In the biopharmaceutical sector it involves activities such as preclinical studies in relevant animal models of disease; *in vitro* and *ex vivo* studies using relevant tissues sampled from the target patient population; and toxicology studies, manufacturing and scale-up activities. This research narrows down and improves the active compounds so that they are suitable for testing in patients, and suitable for commercial manufacture should the clinical testing succeed.

As the name suggests, translational research lies at the boundary of basic research and the R&D activities undertaken by businesses. It is characterised by substantial knowledge spillovers, being relatively early in the development pathway, but is typically more complex and costly than the basic research upon which it relies. In CSL's view, this combination of knowledge spillovers and complexity means that many potentially valuable projects fail to attract the level of resource required to progress further. For example, at CSL we look at over 100 new product opportunities each year. Of these, we choose 5-10% for full evaluation and then fewer still for licensing. Some of those that CSL decides not to pursue could, no doubt, result in significant economic benefits to Australia if they were further developed, but are not

[14] CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System* 4.

[15] *Issues Paper* 9.

sound candidates for commercial development by CSL, or are not yet sufficiently advanced to transition to commercial development.

In CSL's view, greater government support for translational research would increase the pool of high quality projects, which would further boost commercial returns from Australian research. CSL has previously recommended[16] *new government funded Translational Grants to replace NHRMC Development Grants to fulfil this role. These grants would be sizeable (of the order $10m for each supported project) and would be dependent upon a partnership between the research institution and a credible industry partner.*

In CSL's view, the prospects of boosting commercial returns from medical research in Australia would improve substantially if a significant share of the MRFF was allocated on a similar basis to these Translational Grants.

Development

The last stage of the R&D process is the development of the 'proof of concept' or prototype into a commercial product. In the biopharmaceutical sector this typically involves three phases of clinical trials in humans, each of which resolves some aspect of technical risk (such as efficacy, dosage, side effects etc.) followed by regulatory approvals and commercial launch.

The development stage is typically the most expensive stage of the overall process and failure rates are high. The development stage generates knowledge spillovers, particularly in the earlier clinical stages, but they are typically smaller than those of basic and translational research. Accordingly, a greater proportion of the economic benefits of development can be captured by the business undertaking the development. As a result:

- businesses have stronger incentives to undertake development (as opposed to basic and translational research), knowing that the commercial benefits of their expenditure (whether successful or not[17]) will not dissipate to competitors and the wider community;
- the optimum level of government support needed to ensure that there is a sufficient level of development activity by businesses is less (at least proportionately) than is the case for basic or translational research;
- government should support businesses undertaking development, rather than institutions purporting to undertake development activities.

The Commonwealth currently supports development activities through the corporate tax system. CSL has previously stated[18] *that the 45% refundable R&D tax offset for smaller firms*

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[16] CSL (March 2012) *Submission to the McKeon Strategic Review of Health and Medical Research* 6.

[17] Development expenditure that does not result in a product is very often valuable even though superficially unsuccessful. The most famous example of this the failed attempt by a 3M employee to develop a strong adhesive gave rise to the Post-It Note.

[18] CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System* 25.

and the 40 per cent non-refundable tax offset to larger firms represent an appropriate level and of support, and strike an appropriate balance between overly proscriptive definitions of R&D, and the risk of supporting R&D that would take place anyway, without the support. [19]

Business R&D, while treated as an operating expense from an accounting and tax perspective, is in reality a form of investment. Business will increase R&D expenditure (i.e. investment in R&D) if they anticipate earning a higher return from it, and decrease their R&D expenditure if they anticipate earning lower returns. Businesses assess the expected return on investment on the basis of the post-tax earnings that the investment will generate. The beneficial effect of the 40% tax offset on R&D therefore derives from the additional post-tax returns that the business earns as a result of the offset.

Under Australia's system of imputation credits, the increase in post-tax returns earned by Australian shareholders is diluted for listed Australian firms that make profits in Australia. As a result, the incentive effects of the R&D tax offset are similarly diluted. The dilution effect for foreign-owned firms is much less and perhaps negligible.[20] *CSL has not recommended specific changes to the imputation credit system, even though it can obviate some of the benefit of the R&D tax offset for the shareholders of listed Australian firms.*

In CSL's experience, there are often opportunities to develop manufacturing which makes use of existing know how or IP, for example in extending existing global manufacturing at new sites. If these investments take place in Australia, they can help embed Australia more securely into global supply chains. Investments of this type can strengthen Australia's technology clusters, delivering social benefits beyond the private returns that investors can earn from them. Government help can be instrumental in securing these types of projects. This was recognised in 2008 by the Pharmaceutical Industry Strategy Group ('PISG') when it recommended that the government establish a strategic investment fund to contribute to such projects. *CSL concurs with the PISG*[21] *that direct government support in the form of co-investment or support for specific investments, from which CSL has benefited, can be an appropriate means of delivering enhanced commercial benefits from Australian research.*

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[19] Form the reasons set out in Section 6 of our Senate Inquiry Submission (*ibid*), CSL believes that increasing the quantum of overseas expenditure eligible for the offsets would enhance the effectiveness of the concession by increasing incentives undertake later stage development and commercialisation from Australia.

[20] For a more detailed exposition see CSL (April 2008) *Submission to the Review of the National Innovation System*.

[21] CSL (July 2014) *Submission to the Senate Inquiry on Australia's Innovation System* 26.

Incentives to commercialise research

The *Issues Paper* set out a number of possible policy measures that could raise the commercial return from Australian research. CSL endorses most of these as useful measures to help raise the commercial value of Australian research.

Push or supply-side measures

Most of these might usefully be described as 'push' or 'supply' measures, for example: increasing the supply of research that is suitable for businesses to take forward (e.g. translational research); increasing the supply of research scientist to business by rewarding more on business collaboration and less on citation-based research excellence; increasing the proportion of university block funds that are dependent on collaboration with business; increasing the supply of research places in academia that have an industrial component; and increasing funding for translational research.

These types of measures appear to be directed at what appear to be perceived deficiencies in Australia's architecture for commercialising research, such as: the lack of a 'hub' such as those in Silicon Valley and the Cambridge Science Park, notwithstanding the emergence of the Parkville and Monash precents as putative hubs;[22] the lack of intermediaries to facilitate integration of universities and business;[23] the lack of incentives to encourage entrepreneurship;[24] insufficient focus in our research effort on high economic impact areas (even if the research is, itself, high quality);[25] too high a proportion of scientist working in academia rather than business;[26] and lack of funding.[27]

In CSL's view, these are impediments to the commercialisation of Australian research. Indeed, CSL's own submissions have proposed reforms to address them, such as Translational Grants. However, in CSL's view, there is a more fundamental problem commercialising Australia's research which is demand rather than supply driven.

The demand side for research, development and commercialisation

In CSL's view, Australian research in the medical and biopharmaceutical sector, in which CSL operates, is in high demand. This is exemplified by CSL's own experience, acquiring and then developing the IP for Gardasil® in Australia to the point where it was ready for commercial development, and similarly acquiring and then developing IP for the next generation recombinant coagulation products. This is also evident in the high quality of Australian

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[22] *Issues Paper* 6.

[23] *Ibid*.

[24] *Ibid* 7.

[25] *Ibid* 10.

[26] *Ibid* 12.

[27] *Ibid* 16.

medicine which makes Australia an attractive location for participating in clinical trials of new medicines.

CSL has noted the lack of translational research in Australia, and proposed mechanisms for increasing translational research. In CSL's view, this would result in an increase in the amount of Australian research that businesses would choose to take up. Despite the current deficiency, CSL is in no doubt that any good Australian research that does reach the right stage of development through universities and institutes will be rapidly acquired for commercialisation.

However, Australia is not an attractive place from where to commercialise the products of that research. That is, most businesses wanting to serve global markets would not choose to complete the development, and then manufacture those products, from Australia. Fewer still would want to establish an entrepreneurial business based in Australia from which to market those products globally. There is very little demand by global businesses to set up in Australia to undertake late-stage development, commercialisation and manufacture of high value-added products for global markets.

Businesses may and do choose to undertake research and early development in Australia because it is an attractive place for these activities; it has, for example, high quality universities and institutes, a good supply of skilled researchers, English language, and reasonable R&D incentives through the tax system (particularly for foreign owned firms). However, a number of fundamental factors discourage businesses from completing the product development process in Australia. These include:

- high corporate tax rates when compared to peer countries, which are a strong disincentive to high value-added manufacture (i.e. manufacture in which a large proportion of the manufactured product's value derives from IP generated through research and development);
- the relatively small size of the Australian market compared the major global markets of the US, EU, China and SE Asia; and
- relatively high labour costs.

The consequences of this lack of demand, driven by these factors, match many of the deficiencies expressed in the *Issues Paper*. For example:

- Australian research does not usually result in late-stage development and high-value manufacture in Australia. As a result, there is a paucity of high-paying jobs for scientists and engineers in business; scientists and researchers are predominantly found in academia, the research institutes and the CSIRO. This is in direct contrast to, say, Germany;
- the balance of research in Australia is early stage in universities and research institutes, where researchers tend to be rewarded on the basis of citations rather than industrial collaboration or the commercial value of the IP; this is not inappropriate when the knowledge spillovers of good research are very large, as is the case with

basic and translational research. It might well change if business created more demand for research scientists, shifting emphasis towards later stage research;

- the reluctance of businesses to undertake high-value manufacturing in Australia deters the formation of strong hubs like the Cambridge Science Park; and
- the costs (or poor returns) from late-stage development and commercialisation from Australia reduces the likelihood that earlier stage possibilities are worth the risk — the Valley of Death — and reduces the attractiveness of the entrepreneurial path for research scientists in universities and research institutes.

There are some demand side measures in the *Issues Paper*, for example: encouraging academics to form IP spin-offs from universities and research institutes by allowing them to keep a proportion of the royalties that the IP generates; and increasing funding to overcome the 'valley of death' at the point of transition from research to development stages of the product development chain. These measures may increase IP development in Australia, but are unlikely to encourage late-stage development and commercialisation from Australia.

Australia does not reap full value from the IP it generates

Australian research is valuable, even though it is typically early stage. CSL has demonstrated this with its Gardasil® IP and the IP it has generated for its enhanced recombinant coagulation factors. When such IP is transferred overseas for subsequent development and manufacture, this is done on an arm's length basis that reflects the value of the IP at the time of transfer. This might comprise, for example, a payment and an agreed share of the royalties should the products succeed, both of which are taxable and beneficial to the economy.

However, the returns to the Australian economy from these arm's length payments fall short of the gains that would accrue if the products were manufactured and commercialised from Australia. Australia does not reap the benefits of the investment in manufacturing, the increase in skilled employment and the wages they earn, the acquisition of skills in related areas such as compliance with US and EU pharmaceutical regulation, and multiplier effects. There are typically other intangible benefits from manufacture and commercialisation, such as follow-on R&D in related areas, the emergence of new or related products, and clustering effects where other manufacturers are attracted by the availability of resources and skills.

CSL therefore considers that, while many of the suggestions raised in the Issues Paper would be valuable to the Australian economy, not least the doubling of government funding of medical research through the MRFF, the most effective policy for commercialising Australia's research is to make Australia an attractive location for businesses doing late-stage development and commercial manufacture of high value added products for global markets.

Comparator countries

As noted above, business R&D is a form of investment the quantum of which depends upon the post-tax return businesses earn on the products they produce as a result of their R&D. Businesses that have a choice over where they locate high-value manufacturing with a large R&D content (i.e. footloose investment) will select, all other things being equal, locations that

have a low effective tax rate. Typically, new investment by multinational companies servicing global markets is footloose.

It is beyond the scope of this submission to undertake an exhaustive review of differential tax rates between jurisdictions, but a number of countries that CSL has reviewed in making its own investment decisions illustrate differentials in tax rates. In contrast to Australia's corporate tax rate of 30%, the UK is progressively reducing its corporate tax rate to 20%, Ireland has a flat tax rate of 12.5% and Singapore a 17% rate.[28] In addition to low corporate tax rates, Ireland and Singapore offer a range of investment incentives. Singapore offers an exemption from corporate income tax for up to 10 years in return for new R&D investments, concessionary tax rates for companies that relocate their headquarters to Singapore, and tax incentives for R&D. Companies in Ireland pay no income tax on earnings from IP where the underlying R&D is conducted in Ireland.[29] Both of these countries have been able to attract significant levels of inward direct investment despite the relatively small size of their economies. Between 2008 and 2012 Singapore attracted $203.3 billion in FDI inflows, equivalent to 74% of GDP, while Ireland attracted $92.8 billion in FDI.[30] Switzerland, where CSL has decided to locate its recombinant coagulation factor manufacturing facility, has a range of effective tax rates substantially below the statutory rate of around 25% for limited periods, depending on canton and commune.[31]

Tax rates are not the only consideration, nor even the primary consideration, for many investments. Nevertheless, in so far as there are a number of suitable jurisdictions for an investment — say Australia, the UK, Singapore, Ireland and Switzerland — average effective tax rate is very likely to be determinative. Where multiple countries with a similarly favourable investment climate are competing to attract direct investment, tax competition can play a critical role for footloose firms deciding whether to invest in a particular country or region. This echoes CSL's own experience in deciding upon the location of major new investments.

International competition for footloose investment

In CSL's view, Australia will not be able to boost the commercial returns from its public research unless it can encourage businesses to develop and manufacture products based on that research for global markets from within Australia. Corporate tax is a significant impediment to this; in this regard, it is notable that Australia's corporate tax rate is high by OECD standards[32]

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[28] KPMG (2014) *Corporate tax rate survey 2014* http://www.kpmg.com/IE/en/IssuesAndInsights/ArticlesPublications/Documents/kpmg-2014-global-corporate-and-indirect-tax-survey-2.pdf.

[29] AusBiotech (2014) *AusBiotech response to the Competition Policy Review* http://competitionpolicyreview.gov.au/ files/2014/06/AusBiotech.pdf.

[30] UHY (2013) *Singapore and Irelands tax regimes attract world beating levels of FDI* (2013) http://www.uhy.com/singapore-and-irelands-tax-regimes-attract-world-beating-levels-of-fdi/.

[31] KPMG (2014) http://www.kpmg.com/global/en/services/tax/tax-tools-and-resources/pages/corporate-tax-rates-table.aspx (last viewed 17 July 2014).

[32] According to the Henry Tax Review, in 2009, Australia had the third highest statutory corporate tax rate of small to medium-sized OECD economies. *Australia's future tax system: A report to the treasurer*

and Australia is one of the few countries that has not reduced its corporate tax rate since 2005. Recent initiatives in a number of important economies, such as the UK, in relation to the taxation of profits from IP, threaten to worsen Australia's position.

It is likely that relatively large differentials in corporate tax rates are needed to engender a significant change in incentives to commercialise research from Australia. Moving rates modestly towards the OECD average may relatively inconsequential in respect of foreign direct investment (FDI) or in terms of domestic companies investing for exports.[33] However, revenue requirements for Australian governments clearly preclude a substantial reduction in corporate tax rates.

Patent boxes[34] and other incentives for innovation

This problem is not unique to Australia. A number of economies with strong research sectors are revising their system of corporate tax to capture the full benefits of their public research, particularly through mechanisms such as Patent Boxes.[35] The UK Patent Box scheme is a good example, allowing companies to apply a lower 10% rate of corporation tax on profits earned from patents provided the claimant company or another company in the group[36] has undertaken qualifying development for the patent by making a significant contribution to either:

- the creation or development of the patented invention, or
- a product incorporating the patented invention.

(2009) http://taxreview.treasury.gov.au/content/downloads/final_report_part_1/00_afts_final_report_consolidated.pdf.

[33] Bénassy-Quéré et al (2003) CEPII *Tax Competition and Foreign Direct Investment* "…relocating from one country to another is costly. In such a framework, large discrepancies should matter more than small ones. Hence the relationship between tax differentials and FDI may be non-linear, large tax differentials having relatively more impact than small ones." http://www.cepii.fr/PDF_PUB/wp/2003/wp2003-17.pdf

[34] Named as such "because there is a box to tick on the tax form"

[35] It should be noted that some small economies that do not have strong research sectors have introduced similar schemes solely designed to attract investment, without ties to domestically held or generated IP or patents. These include, for example, Cyprus, Hungary and Malta.

[36] 'Group' is broadly defined under the regime. Two companies will be considered as a 'group' if any of the five conditions outlined in CTA10/S357GD are met. http://www.hmrc.gov.uk/manuals/cirdmanual/cird260140.htm

Other EU countries also currently operate patent box (or similar) schemes including Belgium, France, Spain, Hungary, Luxemburg and the Netherlands.[37] Patent Box legislation has also been introduced in the United States.[38]

A Patent Box for Australia?

In CSL's view, in order for Australia to boost the commercial value of its public research, to secure the multiplier and spillover benefits that arise from high value manufacturing, Australia must become an attractive location from which to commercialise that research. From this perspective, Australia has advantages (e.g. English speaking, high levels of skills) and disadvantages (e.g. location, high labour costs), but most importantly has a much higher tax rate on high value manufacturing than peers that are otherwise similarly or better endowed.

In order to maximise the benefits to the Australian economy, including the multiplier and spillover benefits that arise from high value manufacturing in Australia, the corporate tax system must find a model that preferentially incentivises, through a sufficiently low rate, investment in Australia when the investment is genuinely footloose, derived from IP developed to a significant degree in Australia, and results in the late-stage development, commercialisation and manufacture from Australia.

CSL believes Australia requires a scheme to increase the post-tax earnings of enterprises which choose to make footloose investments into Australia, for the development and manufacture of products in Australia that are based on Australian research. In particular, Australia needs to attract entrepreneurial businesses to be based in Australia from which to market those products globally. However, it is beyond the scope of this submission to set out how an Australian innovation incentive, including potentially a Patent Box or some near equivalent, might work. Nevertheless, CSL does not believe that Australia will be able to significantly boost the commercial value of its public research if it does if fails to follow the lead of peer economies with strong public research sectors.

Related submissions

Senate References Committee Inquiry into Australia's Innovation System.
http://www.csl.com.au/docs/813/848/CSL%20Submission%20Senate%20Inquiry%20into%20Australia's%20Innovation%20System.pdf

McKeon Strategic Review of Health and Medical Research.
http://www.csl.com.au/docs/76/51/CSLSubmission_McKeon%20Review_2012web.pdf

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[37] PricewaterhouseCoopers. (2013). Patent box and technology incentives: Tax and financial reporting considerations. Available from: http://www.pwc.com/en_US/us/tax-accounting-services/assets/pwc-patent-box-and-technology-incentives-tax-and-reporting-considerations.pdf [Accessed 7 July 2014].

[38] Evers, L., Miller, H. and Spengal, C. (2013). Intellectual Property Box Regimes: Effective Tax Rates and Tax Policy Considerations. Available from: http://ftp.zew.de/pub/zew-docs/dp/dp13070.pdf [Accessed 8 July 2014].

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