

**PRODUCTIVITY COMMISSION**  
**COMPULSORY LICENSING OF PATENTS**

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**SUBMISSION**

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**THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH**

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## 1. Introduction

The Walter and Eliza Hall Institute of Medical Research (WEHI) welcomes this opportunity to provide input into an important aspect of increasing Australia's competitiveness and productivity – effectiveness in intellectual property (IP) licensing.

We understand that a review of compulsory licensing of patents in Australia is a natural question that evolved from the recent deliberations with respect to “gene patents” and the welcomed “Raising the bar” initiatives introduced by IP Australia.

It is essential that a review of compulsory licensing is in the context of the practical reality of current and anticipated licensing practices, business behaviour and commercialisation activities. While rare incidences from the past may be useful learning (e.g. BRCA1 and Myriad) they do not represent current general practice and in fact are rare anomalies in what is a well-functioning market system. It would be dangerous to be distracted by theoretical or hypothetical concerns in the belief that they address what is, in our opinion, a very rare, even anomalous issue in practice.

Therefore, a review of IP and compulsory licensing in Australia must be undertaken with respect to three critical contexts:

- a) Firstly, Australia seriously underperforms with respect to patenting and patents are central to any licensing activity (Appendix 1). Australia's performance in publication of science results is not matched by a commensurate focus on the most critical step to translation – patenting and subsequent licensing.
- b) Secondly, in the last decade or so there have been to our knowledge only four attempts to invoke compulsory licensing in Australia and all were unsuccessful. With a national intellectual property estate of more than 250,000 issued patents<sup>1</sup> this rate of interest in compulsory licensing must tend to zero in terms of national productivity, economic significance and priority.
- c) Thirdly, Australia's resident licensing activity is significant based on review of 58 public organisations, including CSIRO<sup>2</sup>. These organisations had 10,400 issued and pending patent applications and had entered into more than 4,500 license, option and assignment agreements since 2000. None were involved in compulsory licensing proceedings.

As a consequence, further development and encouragement of compulsory licensing provisions should be viewed as a diversion from productivity and returns from Australia's investment in science. Consequently we remain strong advocates of maintaining the current situation with respect to the compulsory license and related provisions in Australian law. Increased efforts should rather be focused on improving Australia's track record in patenting and translation of its investment in science.

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<sup>1</sup> Resident and non-resident

<sup>2</sup> Commonwealth of Australia (2011) National Survey of Research Commercialisation 2008/9

## 2. Overview of WEHI's patenting and licensing activities

Founded in 1915, WEHI is Australia's oldest medical research Institute (MRI) and has a strong track record of research, capture and management of intellectual property and translation of research into medical outcomes. We have extensive experience of the Australian and international patent systems. WEHI currently invests more than \$90 m per year in medical research. Most of these funds are provided by public funding agencies such as NHMRC<sup>3</sup> and NIH<sup>4</sup>. Our research efforts are underpinned by more than 700 full-time equivalent employees and post-graduate students. Approximately 80 research laboratories focus on major medical challenges associated with cancer, immunity, autoimmunity, inflammation and infectious disease. We have extensive research collaborations and licenses with private sector partners such as Genentech, Abbott Laboratories, Becton Dickinson and Merck in the US, Cancer Research Technologies in the UK, GSK in Belgium and CSL, Bionomics and Cancer Therapeutics CRC in Australia.

As a not-for-profit, tax exempt research institute, our core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. As a consequence we place great emphasis on publications, and have the highest citation impact of any organisation in Australia<sup>5</sup>. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most of our funds. Furthermore, any benefit that derives from commercialisation and exploitation of institute-derived IP is insufficient to compensate for the funding gap that still exists after receipt of public and private research revenue, and government infrastructure support. To date, this funding gap has been filled by returns from accumulated bequests and donations.

WEHI's activities are underpinned by a generally strong organisational understanding and engagement with the global IP system. Importantly, our initiatives to improve translational outcomes include a) in-house patent prosecution, b) a business development intern scheme for early career scientists, c) routine laboratory notebook audits, and d) a small fund for investment in proof of principle experiments. WEHI's discovery and innovation pipeline is fed by a portfolio of more than 250 research projects and in the last 11 years we have:

- Contributed more than 2,500 highly cited publications
- Entered into approximately 2,400 Material Transfer Agreements with academia and industry
- Evaluated 200 significant invention disclosures
- Lodged more than 130 patent family applications
- Entered into more than 485 commercial agreements, the majority of which include IP and licensing provisions

WEHI's model for engagement with commercialisation partners is pragmatic and flexible. At any one time several licensing discussions are ongoing and these result in collaborative development agreements with established companies, small and large, as well as the creation of new spin out companies such as Genera Biosystems, Nexpep/ImmusanT, Murigen, BACE Therapeutics and Catalyst Therapeutics.

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<sup>3</sup> National Health and Medical Research Council

<sup>4</sup> National Institutes of Health (US)

<sup>5</sup> King C (2007) *The large and small of Australian research* ScienceWatch 18(5)1-2

The fundamental driver for WEHI is to achieve outcomes from research investment, recognising that the risk of investment in translation activities high. In general WEHI seeks ongoing collaborations and engagement with commercial partners since our intellectual property is rarely “market ready” and requires further “reduction to practise”. WEHI has not had any reason to consider or be involved in compulsory licensing.

### **3. Extent and nature of patent licensing**

No Australian public research organisation can afford to keep collecting patents without attempts to exploit and license. Therefore, the extent of patent licensing activities must be regarded as being extensive in the Australian context.

A key explanation for Australia’s relative poor performance in patenting (see Appendix 1) is that funds are not available to support patenting activities for potential inventions from the public sector. Most public research organisations therefore will capture invention disclosures but be often forced to abandon provisional patent applications if they are not partnered before the PCT application. It is relatively rare that a public research organisation in Australia will continue with National Phase prosecution of a patent if it is not partnered. In most cases patent licensing activities will include negotiation for the commercialisation party to fund patent prosecution.

This means that Australia’s public research organisations focus heavily on patent licensing and early partnering. Most IP from Australia’s research organisations is at an early stage and is rarely “market ready”. As a consequence potential revenue streams are a long time in the future and issues of compulsory licensing for exploitation naturally have little significance since revenue streams have rarely materialised.

To our knowledge, most public research organisations, and certainly WEHI, focus on finding the most appropriate partner for translation, Australian or foreign, small or large, and ultimately settle on “optimal” and practical rather than “maximal” licensing terms due to the early stage of the IP.

### **4. Features of a licensing agreement**

The concept of a “stand alone” license agreement in biomedical research is somewhat out-dated due to the usually early stage of IP and complexity of the biology. As a consequence licensing provisions have become commonly embedded in a range of associated agreements such as collaborations agreements, research support agreements, option agreements and even material transfer agreements.

In WEHI’s experience over the last few years, Appendix 2 presents the most common terms in an agreement that includes licensing provisions. There can be wide variations in the way in which these issues are presented but there is a common thrust based on returns, risk, performance, liabilities and termination.

### **5. Incentives to license an invention**

There is of course significant asymmetry in licensing patents. Large, well-resourced patent holders will seek to exploit patent monopolies under their own terms and usually internally. Public research organisations and small companies are, on the other hand, dependent on licensing as a route to translation and eventual returns.

Ultimately, for all players incentives for licensing are based on:

- Exploiting an unmet market need
- Investment to secure translation outcomes
- Bridging the “valley of death”
- Demonstrating potential community benefit

- Achieving a return on tax payer investment in research
- Demonstration of “shareholder” and “stakeholder” value

The terms of a license agreement (e.g. as exemplified in Appendix 2) tend to be generic irrespective of Licensee size. It should be noted that a large company may have the resources to maintain patents to reduce competition even though they do not exploit reasonably such patents. In recent years we have not seen evidence of such behaviour.

There are enormous incentives for WEHI to license its inventions. As a not-for-profit research institute, WEHI's core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. We are committed to translation of our discoveries, both clinically and commercially. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most of our funds. The critical issue is effective translation of knowledge into community outcomes, whether in Australia or globally.

Public institutes do not have the skills or capital to transform research results into marketable products in the form of pharmaceuticals, therapeutic proteins and diagnostics and therefore require private sector involvement to make possible public access to these developments. Consequently, WEHI works with other organisations to achieve these outcomes through effective licensing practices and collaborations. Commercial returns are fed back into further research at WEHI.

As discoveries are made and intellectual property is identified, resulting inventions are partnered with development collaborators to progress into the clinic and market place. The use of exclusive licensing with the option to sublicense has proved effective for getting products into the market.

## 6. Current use of compulsory licensing

To our knowledge, compulsory licensing is extremely rare with little or no precedent in Australia with only rare examples of Crown use decisions. The Patents Act provides that at any time after a patent application has been lodged or a patent granted, the Commonwealth or State, or a person authorised in writing by the Commonwealth or a State may exploit the invention without infringement provided the exploitation is for the services of the Commonwealth or State. Crown use has been upheld in two Australian decisions, *Stack v Brisbane City Council* and *General Steel Industries Inc v Commissioner for Railways (NSW)*. These cases involved the use of patented inventions in water meters by local government: *Stack v Brisbane City Council* (1994) 131 ALR 333; and central bearing structures for railway carriage construction by a state Commissioner for Railways: *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125.

With around 75,000 researchers, more than 250,000 patents granted in Australia and more than 4,500 commercial agreements with public research organisations since 2000, compulsory licensing considerations are insignificant given the commercialisation activity.

In our opinion the lack of compulsory licensing applications is a sign that the system is working, not that anything is wrong. Common sense and ultimately the market place address commercialisation and access issues. We have not experienced any issues with licensing in at least the last ten years.

The current provisions and lack of precedent mean that there is uncertainty due to high cost and uncertain delays, with no known way of estimating the prospect of success or financial return. There is a deterrent aspect with the current provisions that places emphasis on business resolution of issues should they arise. Any potential litigant would explore the ramifications and in the absence of Australian data would know that, for example, in the US patent litigation is likely to

involve 4.5 years, median damages of \$10 – 12 m, a jury trial and an initial budget of \$3 – 5 m and no guarantee of success<sup>6</sup>. There is no reason to believe that compulsory licensing in Australia's courts would be less onerous in the absence of precedent and we believe that common sense and business imperatives explain the lack of interest in compulsory licensing litigation.

## **7. Current compulsory licensing provisions**

We find the current provisions for compulsory licensing to be sufficiently clear unless the objective is to encourage greater legal activity. Our understanding is that the court may award a compulsory license if:

- The applicant has tried for a reasonable period to obtain a license on reasonable terms;
- The reasonable requirements of the public with respect to the patented invention have not been satisfied; and
- The patentee has not given a satisfactory reason for failing to exploit the invention.

The reasonable requirements of the public may be considered not to have been met if an industry or trade in Australia is unfairly prejudiced, or the demand for the patented product or process is not reasonably met because of the patentee's failure to:

- Manufacture the product or part of the product to an adequate extent, and supply it on reasonable terms;
- Carry out the patented process to a reasonable extent; or
- Grant a license on reasonable terms.

The Intellectual Property Laws Amendments Act 2006 enables a court to grant a compulsory license if the patentee is acting anti-competitively in contravention of Part IV of the Trade Practices Act 1974 or an application law as defined in Section 150A of that act. That is, if a patentee engages in anti-competitive conduct such as price-fixing, misuse of market power and exclusive dealing. A compulsory licence has not been granted in Australia since Federation and the threat of a compulsory licence presumably acts as a deterrent and has the effect of encouraging patentees to work their inventions or enter into licensing arrangements. The Federal Court may grant a licence where it is established that all of the conditions under subsection 133(2) exist.

In a practical sense legal deliberations will revolve around the meaning of "reasonable". We are not aware of any actual cases that would require or have benefited from further clarification of the objectives of the compulsory licensing provisions.

## **8. When would a patent holder deny a license?**

It is generally thought that a patent holder may refuse licensing to impose high prices, restrict access and block dependent patents and that compulsory licensing may assist in providing access for the broader public interest. However, a compulsory licence has never been granted in Australia and WEHI has effectively negotiated licensing arrangements with many partners to achieve clinical outcomes for our research. Importantly, this would indicate that to a major extent the market forces driving prices are acceptable.

A patent holder would deny a licence if:

- The patent holder intends to work and commercialise the invention themselves;

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<sup>6</sup> PWC (2011) Patent litigation study: Patent litigation trends as the "America Invents Act" becomes law.

- A proposed licensee does not have an appreciation of the value of the IP or relevant experience in commercialising in the field;
- A proposed licensee offers terms that are significantly different from market practise at the time of negotiations;
- A proposed licensee is likely to not work the invention; or
- A proposed licensee has a poor ethical track record

Typical clauses in a license agreement are illustrated in Appendix 2 and one of the most important areas to consider when licensing is that of performance of licensee.

## 9. How to use compulsory licensing for gene patents and other specific technologies

We believe that a patent and licensing system must be inherently technology neutral. Why would Australia suddenly single out gene patents for compulsory licensing ten years after the peak in human gene patents<sup>7</sup>, in the face of declining human gene patent maintenance<sup>8</sup>, and a total lack of petitions for compulsory licensing or Crown use? The patent and licensing systems have been faced with new technologies for more than two hundred years and will address many more new technologies without the need for specific technology exemptions. Any major issues, and to date there have been none, can be addressed by the current compulsory licensing and Crown Use provisions.

Each of the examples of areas of concern expressed in the issues paper, genes, food security, climate change mitigation and alternative energy, will change much more rapidly than our ability to legislate and then keep current with appropriate definitions. Why would these areas be selected rather than others, and in the face of no evidence for a need to “quarantine” technologies? We see no advantage and a major disadvantage for such an approach that would introduce an unwarranted clear disincentive for commercial development for no community benefit.

We argue that arbitrarily exempting certain areas and technologies would further erode Australia’s poor track record in IP performance. The fact that compulsory licensing provisions have not been used in Australia, suggests that licensing practices in Australia are in fact working effectively. Under the *Patents Act*, a prescribed court may grant a compulsory licence to work a patent if it is satisfied that the “reasonable requirements of the public” with respect to the patented invention have not been satisfied. The ALRC was not aware of any compulsory licences having been granted since Federation and none in other jurisdictions (e.g. UK, Japan, NZ, Canada) at least since 1993.

The ALRC considered that where particular gene patent applications are believed to have an adverse impact on medical research or the cost-effective provision of healthcare, health departments should consider legal intervention, including challenging and exercising Crown use powers. WEHI notes that such options have always been open. However, WEHI submits that the cost and ramifications of a government department challenging issued patents would need to be seriously considered particularly in the light of the need for evidence of restricted access and harm. For example, an Australian public provider of a diagnostic test may challenge a private provider who charges more for the same test. How confident is the Australian public organisation that it has accurately costed its test, how much of the overhead is still being subsidised by the tax payer, and does it comply with the requirements for competitive neutrality? Such actions are likely to have significant ramifications in areas beyond genes, diagnostics and healthcare.

<sup>7</sup> IP Australia patent application and grant data

<sup>8</sup> Mills AE, Teresberg P (2010) Human gene patent renewals on the decline. *Nature Biotech* 29:711

## **10. The case for clarification and change**

We submit that there is little need for clarification and no need for change to compulsory licensing and Crown Use provisions. Crown Use provisions restrict and encroach the rights of the patentee to exploit the invention exclusively and consequently, should only be cautiously considered in situations of public health emergencies and for defense purposes. A strong patent system is essential to provide the incentive for investment in research, development and technology transfer.

Crown Use provisions provide a safeguard to any adverse impact of patent protection on public interest. These provisions should be used cautiously and for exceptional circumstances only since undertaking research and development in biomedicine is risky and expensive. Under the Crown Use provisions the patent owner is entitled to just and equitable compensation for Crown Use as agreed mutually or in the absence of an agreement, as determined by the Courts under s163 of the Patents Act. Such compensation must take into account costs of development, loss of exclusivity and likely loss of future income since public bodies are rarely effective at commercialisation.

Enhanced compulsory licensing could make investment in patenting and development less secure. If compulsory licensing is promoted beyond necessity, then companies would be less inclined to invest in expensive research and development. It is hard to imagine that promotion of simpler routes to compulsory licensing would improve productivity in Australia, enhance translation of science investment into major outcomes, or provide a benefit to the community.

With respect to clarification, the ALRC recommended that the Commonwealth should amend the *Patents Act* to insert the Intellectual Property and Competition Review Committee's competition-based test as an additional ground for the grant of a compulsory licence. This test would address those circumstances in which there is a public interest in enhanced competition in a market, and the patent holder has not met reasonable requirements for access to the patented invention. The ALRC did not consider it necessary to recommend any reforms to the compulsory licensing provisions to address circumstances involving dependent patents, and also did not consider it necessary to recommend any reforms to the compulsory licensing provisions to address circumstances of emergency, or public non-commercial use of patented inventions.

Any case for change, and we believe there is none, must address the question of how new costs, additional governance and potentially new bodies and legal structures could be justified or given priority when there is no demonstrable need to address something that has not occurred and is unlikely to occur outside current provisions.

## **11. Awareness of compulsory licensing**

WEHI maintains that any qualified IP professional in Australia would be aware of compulsory licensing and Crown Use provisions under Australian law. In our experience Australian companies, small and large, universities and medical research institutes use such professionals on a routine basis and would therefore be directly or indirectly aware of options for IP exploitation. The extent to which decision makers in public healthcare organisations are aware of these provisions is unknown to WEHI.

We conclude that, in general, awareness of compulsory licensing is not an issue. Importantly, why would Australia want to invest in promoting provisions that have rarely been used and for which there is apparently no market, appetite for litigation or return to the tax payer?

Further we do not understand why the issues paper suggests that there should be specific awareness and promotion activities directed to small businesses and the healthcare sector. Is the purpose to encourage litigation when it has not previously been required? Why promote litigation opportunities to the segments that can least afford or justify such action?



In the interest of Australia's productivity, return on investment in science, and competitiveness, it is strongly recommended that there is focus on improving patenting, translation performance and communicating the advances in "Raising the bar". Investment in changing provisions for compulsory licensing and promotion thereof would be distractions and a misuse of scarce funds.

## 12. Alternative mechanisms

Proposing an alternative mechanism for something that hasn't occurred is a challenge and it is strongly recommended that a rigorous cost/benefit analysis be conducted for any change from the present system. It is difficult to understand how an alternative dispute resolution body could facilitate applications at less cost because it is likely that representation, due diligence and evidentiary material will still be required. Arguments against compulsory licensing would generally focus on insufficient compensation for the large costs of development and encroachment of rights to exclusivity. Importantly, they would focus on cost structures, reasonable margins and competitive neutrality issues.

Section 51(3) of the CCA exempts conditions in intellectual property licences and assignments as they relate to the intellectual property. Section 51(3) was inserted to protect valid IP arrangements. The exemptions do not apply to the misuse of market power (s46) and resale price maintenance (s48) and therefore this mechanism exists.

Government purchasing power may provide mechanisms to control the availability and cost of medical testing, including those costs that may be attributable to patent rights<sup>9</sup>. The ALRC recommended that the Australian Health Ministers Advisory Council should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare. WEHI is of the strong belief that the analysis and subsequent exercise of purchasing power must be coordinated at the national level and that appropriate economic analysis will also inform conditions to be negotiated for purchase. The challenge is not compulsory licensing or patent rights, but rather the division between national purchasing through an extended version of the PBS to include for example, genetic tests, and the payment by state-based pathology laboratories for genetic tests.

## 13. Recommendation:

WEHI has reviewed the issues paper from the Productivity Commission and has been an active contributor to previous Australian IP reviews<sup>10</sup>. Furthermore, WEHI is an active participant in Australia's attempts to translate and commercialise investments in biomedical research. Therefore, our recommendation is to maintain the current compulsory licensing provisions based on the view that:

- There has been little need for and no successful action under compulsory license provisions
- Market forces encourage acceptable licensing practices without recourse to litigation
- There is no evidence that compulsory licensing litigation should be encouraged or would produce a productivity lift for Australia
- There is no evidence that compulsory licensing of selected technologies would enhance Australia's reputation or equity of access for our citizens

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<sup>9</sup> This already occurs through the monopsony on pharmaceuticals for the PBS

<sup>10</sup> Intellectual property laws amendment (raising the bar) bill 2011 (WEHI submission April 2011)  
Senate legal and constitutional affairs legislation committee inquiry into Patent amendment (human genes and Biological materials) bill 2010 (WEHI submission January 2011)  
Senate community affairs committee Inquiry into gene patents (WEHI submission March 2009)  
Advisory Council on Intellectual Property "patents and experimental use: issues paper" (WEHI submission April 2004)  
Australian Law Reform Commission Issues paper: gene patenting and human health (WEHI submission February 2004)

- Emphasis should be placed on raising Australia's relatively poor performance in IP prosecution and licensing
- Any funds contemplated for compulsory licensing should be redirected into strengthening Australia's weak IP culture, making it more competitive and less protective.

## Appendix 1: Australia's relative IP performance

<b>Metric</b>	<b>Australia</b>	<b>US</b>	<b>Sweden</b>	<b>Source</b>
Scientific articles per million	791	725	1,143	1
Triadic patents per million	19	53	81	1
Resident patent applications per \$bn GDP	3.7	17.8	8.2	2
US patent applications per \$100m R&D	1.5	6.6		3
% of triadic patents	0.64		1.64	4
% of highly cited articles	4.0		2.5	5

1. OECD (2010) Science, technology and industry outlook
2. WIPO (2010) World intellectual property indicators
3. Commonwealth of Australia (2011) National survey of research commercialisation
4. OECD (2010) Main science and technology indicators
5. OECD (2010) Measuring innovation: a new perspective

## Appendix 2: Overview of typical biomedical licensing agreement clauses

The following items are typically included in licensing agreements in the biomedical sector. This overview does not consider “contract research” where the terms are vastly different and understandably asymmetric with all power lying with the contractor.

It is increasingly common that these term areas are included in Collaborative R&D Agreements (CRADA) that combine the terms of the license with ongoing collaboration project research support. This is because the IP is rarely “technology transfer ready” and an ongoing relationship is required to secure value and support for development and validation activities. In its executed form each agreement is unique and the following term areas will have different emphases depending on the situation and partners. The presentation of the terms as legal clauses in a license agreement varies between jurisdictions (e.g. US, Europe, Australia and Japan), however, the underlying legal concepts are the same.

### 1. Key definitions

Each agreement will define the key concepts in the agreement and the critical issues for a licensing agreement include:

Background IP – Definition of what is “in or out” of the license agreement is essential and this Background IP will also be the subject of valuation negotiations. This definition is usually supported by a schedule listing patents, materials and knowhow that are considered to be part of the agreement.

Field - Usually agreed to avoid unintended “reach-through” and define precise scope of the license and related exploitation. Normally, the licensor will want to keep as narrow as possible, while the licensee will strive for breadth.

Net revenue – This definition must define agreed deductions from gross revenue received by the Licensee. Trade discounts and samples need to be agreed.

Related parties – The legal structure of the Licensee must be understood and defined, including the rights and roles of affiliates.

Sub-licensing rights - The right to engage third parties for services, development, and exploitation according to a definition of a Third Party or Affiliate.

Term - Usually for the life of each patent in a defined territory from the date of Commencement and is often expressed as the later of twenty years from the Commencement Date or the last day the licensed patent expires or a longer period as mutually agreed unless earlier terminated.

Territory - Normally licenses are global but they could include territory “carve-outs”. A critical issue is to ensure consideration of major emerging territories (e.g. Brazil, India, China and Russia) as well as the traditional licensing territories (North America, Europe and Japan).

Type of license - Defined as non-exclusive, exclusive, or sole.

### 2. Payments

License and Collaboration agreements can take many forms with respect to returns to the Licensor. The most common considerations include the following, often based on precedent and prevailing market conditions:

- a) Upfront payment for access to the Background IP
- b) Milestone payments according to a Project Plan having defined value adding stages
- c) A defined share of any commercialisation income receive by the Licensee other than direct royalties on sales
- d) Royalties – these can be for example fixed, increasing, decreasing, or milestone/threshold based
- e) Provisions for “royalty stacking” in the event that access to other IP is required for commercialisation
- f) Definition of returns in the event that there is a “combination” product requiring IP from other parties
- g) Annual minimum payment – often part of the Performance Provision and this may or may not be credited against royalty payments.
- h) Other support, either direct (e.g. collaboration R&D support) or in-direct (e.g. in-kind or material compensation from the Licensee)
- i) Equity considerations in lieu of cash may be involved in the above, particularly when the Licensee is a small company.

Any licensing negotiation will consider these various terms in aggregate and lead to trade offs. For the Licensor high development attrition rates will place focus on near term money, i.e. upfront and early milestone payments at the expense of less down stream royalty. For the Licensee high development attrition rates will place focus on downstream money. Small biotech companies have less ability to pay upfront and early milestone fees and will argue that the money should be invested in the development program. Both parties will usually determine the value of the transaction in terms of a risk-adjusted net present value based on a discounted cash flow that is calculated using weighted average cost of capital and industry metrics for the given type of product and therapeutic/diagnostic area.

### **3. Sales of Products**

The licensee must ensure that sales of Products are on Proper Commercial Terms and reasonable quantities are allowed as free samples (promotional or otherwise) or as donations (for example, to nonprofit institutions or government agencies for a non-commercial purpose).

### **4. Currency**

The currency for all payments should be defined and is often based on the currency of trading origin for milestone and royalty payments and currency of Licensor origin when research support is provided. When possible and Australian Licensor will secure research support funds at a fixed AUD rate and be prepared to receive commercialization returns in the Licensee’s nominated currency.

### **5. Project management**

The Licensee is responsible for decisions related to the development and exploitation of the IP. When a licensing collaboration is established, terms for project management and governance must be agreed. These terms relate to a Project Management Committee, frequency of meeting, reporting, changes to plans and decision-making.

Related terms usually include reference to skilled personnel, personnel changes, and record keeping compliant with laboratory notebook requirements.

### **6. Rights over materials**

The Background IP and collaboration may involve Materials (e.g. reagents, strains, etc) where rights of access need to be defined. Access to Materials may well be non-exclusive even though

the License IP is exclusive. Future access to Materials may also need to be defined within the Field.

## **7. Improvements**

The agreement needs to define what happens in the event that the Licensor creates Improvements to the Background IP or Project IP. Usually these are offered to the Licensor since the basic rights to Background IP exploitation will dominate. The parties will need to agree terms for new IP that is related to the Field but may not be specifically covered by the terms. This is often considered through an Option and an Option Period.

## **8. Retained rights**

An academic Licensor will usually require retained rights to the Licensed IP for research and education purposes, subject to confidentiality clauses in the license agreement. Such retained rights usually refer to Background IP, Improvements and Collaboration or Project IP.

## **9. Reasonable commercial endeavours and performance obligations**

This is a critical term to ensure that a license requires active and reasonable attempts to exploit the IP. The main concern of the licensor is that a licence is taken to extinguish exploitation of potentially competing IP. The obligations are usually expressed in terms of activities, milestones, and minimum royalty payments.

Usually, reasonable commercial endeavours must be used to commercialise the Licensed Patents and Project IP; and to promote and develop the sale of the Products under Proper Commercial Terms.

## **10. Reversion for non-performance**

If Licensee does not meet its performance obligations and fails to rectify such alleged under performance within an agreed timeframe the Licensor may:

- a) Limit the Territory
- b) Limit the Field
- c) Convert the license to non-exclusive
- d) Exclude certain Background IP or Improvements

## **11. Applicable Laws**

All Products derived from the Licensed IP or Activities must be made or sold in accordance with all Applicable Laws. The definition will usually refer to accepted regulatory, ethical and legal standards.

## **12. Project IP**

Licensor will disclose Project IP as soon as reasonably possible to Licensee. Intellectual Property in the Project IP shall usually vest on creation in the Licensee noting that the Licensor usually retains rights over the dominating Background IP. It is not uncommon that the Project IP vests with the Licensor, is prosecuted by the Licensor and is exclusively licensed to Licensee.

## **13. IP prosecution and infringement**

There are usually “standard” provisions with respect to IP management and these include:

- a) The Licensee is responsible for and pays for patent prosecution and will be responsible for obtaining and maintaining the Licensed Patents including patent filing, patent

- application prosecution and any other patent application costs as well as ongoing maintenance fees.
- b) Any IP not prosecuted by the Licensee reverts to the Licensor. Should the Licensee decide to lapse any of the Licensed Patents, it will notify the Licensor of this decision and give the Licensor an opportunity to continue with that patent or patent application at their expense.
  - c) The Licensee undertakes not to challenge the licensed IP
  - a) The parties will consult with respect to litigation, which is usually funded by the licensee

Usually the Licensee will have the first right, at its own cost, to take any legal action it deems necessary or advisable to eliminate or minimise the consequences of either:

- a) Potential infringement of the Licensed Patents or Project IP; or
- b) Potential infringement by the Commercialisation of the Licensed Patents or Project IP.

Each party will co-operate fully and promptly with, and provide all reasonable assistance to, the other party in respect of any action brought by or against the other party in relation to that potential infringement.

#### **14. Settlement**

A Party shall not settle or compromise any legal proceedings without the consent of the other Party if the settlement or compromise would have a material legal or commercial impact on the other Party or obliges the other Party to make any payment or part with any property or assume any obligation or grant any licence or other rights.

#### **15. Technology or Background IP assignment**

The license agreement may provide for assignment of the Background and Project IP to the Licensee subject to a defined major event such as significant capital raising, listing on a stock exchange or exceeding a share value threshold.

#### **16. Warranties and indemnities**

Licensor warrants and represents to Licensee that it is free and entitled to grant the licenses and it will not assign, encumber or otherwise deal with Licensed Patents and its Background Technology, except with the prior written approval of the Licensee.

Licensor indemnifies Licensee, its officers and employees and keep them indemnified from and against any loss or Claim suffered or incurred directly or indirectly from a breach of the warranty to entitlement.

Each of the Parties represents and warrants to the other Party that each of the following statements is true and correct in all material respects:

- a) it has full power and authority to enter into, perform and observe its obligations under the Agreement, and that its execution, delivery and performance of the Agreement has been duly and validly authorised by all necessary corporate action;
- b) the Agreement and the transactions contemplated by it do not contravene its constituent documents or any law, regulation or official directive or any of its obligations or undertakings by which it or any of its assets are bound or cause a limitation on its powers or those of its directors to be exceeded; and
- c) to the best of its knowledge at the date of the Agreement, all information provided by it to the other Party is true and not misleading in any material respect.

The Licensor warrants to the Licensee that to the best of its knowledge as at the Commencement Date:

- a) it is the sole legal and beneficial owner of the Background IP and that Background IP is not encumbered nor licensed to a third party; and
- b) it is entitled to grant the rights contained in the Agreement in relation to the Background IP.

Neither Party warrants to the other Party that the first Party has conducted any searches related to patentability or infringement and the Licensor does not warrant that the Background IP may have patent claims granted other than those granted on the Commencement Date. The Licensor does not warrant that the Background IP or Project IP does not infringe other IP positions.

The Licensor makes no warranties as to the merchantability or fitness for purpose of any Product.

Licensor warrants that it has the requisite expertise, skill and facilities to carry out Licensor's research obligations in accordance with a Collaboration Agreement and will maintain that requisite expertise, skill and facilities for the Project Term.

## **17. Liability**

The academic licensor will seek a cap on liability and this is sometimes in conflict, for example, with a US commercial position to have no cap. This cap is essential for academic organisations since their core business is not commercial exploitation, but rather research and education. The actual cap will be guided by insurance policies in force.

## **18. Insurance**

Both parties will need to have adequate insurance with respect to public liability and professional indemnity. The Licensee will need to prove insurance cover, for example, for clinical trials and product liability. Particular attention may need to be given with respect to insurance for USA related activities and Licensees.

## **19. Conflict resolution**

The parties must agree in advance the procedure for addressing disagreement and conflict. The parties shall without delay and in good faith attempt to resolve any dispute or difference which may arise between them in relation to the Agreement.

The usual approach is to use parallel escalation through the party's management ranks. Failing resolution a third party can be appointed and the determination is usually binding. Several third parties may be agreed and a common example is the Licensing Executives Society.

## **20. Termination and reversion**

Both parties to the licensing agreement will seek criteria for termination. They are usually related to financial solvency and compliance with the terms of the agreement, including performance. A termination notice from either party usually provides for a period for remedy before termination is actualised. The act of termination then precipitates the flow-on issues of reversion rights that must be defined. It will be necessary to define rights to ongoing exploitation of Background IP, Project IP, Collaboration IP, Improvements and potential recognition post-termination.

If collaboration or commercialization is discontinued, then notice must be given to the licensor (generally 90 days). The parties will meet and negotiate in good faith the future



commercialisation and respective rights of each party. If the parties are unable to reach a continuing agreement within a given period, either party may immediately terminate. Where the Agreement is terminated:

- a) any further licence fee payment will no longer be payable; and
- b) the Licensor is provided a royalty-free perpetual irrevocable non-Exclusive licence to Commercialise the Project IP and any Improvements and any other IP relating to Project IP and improvements that would otherwise be infringed by Termination.

Certain clauses, such as confidentiality and use of name, survive termination of the Agreement.

## **21. Third party relationships**

The Agreement must define the relationship with third parties for both the Licensor and the Licensee. Typical concerns for an academic Licensor are the needs for ongoing collaboration with non-commercial third parties. The Licensee clearly wants interactions with potential commercial third parties to be closely controlled to preserve the likely commercial exclusivity of the agreement.

## **22. Permitted activities**

Definition of non-competition is usually required to confirm licensor's permitted activities. These may range from clear non-compete provisions within the Field to an Option or Right of First Refusal to the Licensee of new IP in the Field.

## **23. Confidentiality**

Confidentiality provisions are standard with respect to the technology, business plan and agreement terms.

Usually no party shall (without the written consent of the other party) disclose the terms of the Agreement or any Confidential Information of the other to any third party or use any Confidential Information of the other party except for the purpose for which it was disclosed, except for disclosures:

- a) in the form of scientific publications expressly permitted under the Research Agreement; or
- b) required by law (including the ASX listing Rules) or government authorities;
- c) to sublicensees, agents, contractors and employees or financial and insurance or legal advisers on a need to know basis and provided they agree to be bound by obligations of confidentiality; or
- d) reasonably necessary in connection with:
  - a. filing or prosecuting patent applications;
  - b. prosecuting or defending litigation;
  - c. seeking regulatory approval of a Product

## **24. Publication**

Publication of any information relating to the Background IP or Project IP is subject to approval by the Licensee, usually with a timeline compatible with ascertaining any new IP position. It is increasingly common that such publication provisions are reciprocal, requiring approval of both the Licensor and Licensee.

Typically the Licensor and/or Licensee reveal the information to be published, at least 30 days prior to each presentation or submission for publication (including revised submissions),

A specified response time, often up to 90 days is required to enable the Parties to secure any patent protection they deem desirable.

## **25. Use of name**

A party must not use another party's name or other indicia (including without limitation, logos) without the prior written consent of that other party. This provision is often used to manage "implied" or "reach through" endorsement by either Party.

## **26. Reports**

Within an agreed period after the end of each Half Financial Year (often 60 days, and occasionally quarterly), or where the Licensee has a Sublicensee no later than thirty (30) days after Licensee receives payments and reports from its Sublicensee, the Licensee will submit to Licensor a written report summarising Commercialisation activities engaged in by Licensee, its Sub-licensees and its agents and sub-contractors, and providing calculations as relevant of Net Sales Income, Commercial Income and the total sum payable to Licensor during that Half Financial Year in a format agreed by the Parties from time to time.

Licensee undertakes to use reasonable efforts to ensure that any Sublicensee will submit to Licensee a written report within a defined period after the end of each Half Financial Year summarising the information required for Licensee to fulfill its obligations.

## **27. Books and records**

Licensee will keep full and complete books and records in accordance with good accounting practice so as to record all details relating to income and expenditure (including without limitation the number of Products sold by Licensee or any Sub-licensee, the Net Sales Income and the Commercial Income) and upon the provision of reasonable notice, will permit and allow Licensor, its duly authorised representatives and its accountants to have access to such books and all records upon which the same are based during all normal business hours, for the purpose of checking and verifying any and all statements supplied by Licensee to Licensor.

Licensee shall ensure that any Sub-licensee shall keep complete and accurate records in sufficient detail to enable any royalties payable to be determined and verified, including the right to audit at least the previous 3 years accounts.

Provisions describe the process for recovering underpaid royalties due to Licensor.

## **28. Amendment and assignment**

The Agreement can only be amended, supplemented, replaced or novated by another agreement signed by the parties.

The Licensor may also wish to include a change of control clause or its equivalent, requiring approval of Licensor to transfer the agreement to a new legal entity.

## **29. Force Majeure**

The Parties agree to Force Majeure provisions including reporting, action and recovery period.

### **30. Jurisdiction**

Australian licensors prefer a governing jurisdiction according to the laws of one of the Australian States. International licensees prefer their own domestic jurisdiction and this can introduce significant uncertainty for the Australian licensor. The desirable end point in a negotiation is to agree a jurisdiction that is most like English law.