# CSIRO Submission 15/552

## Intellectual Property Arrangements – Draft Report

## Productivity Commission

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**Productivity Commission – Intellectual Property Arrangements, Draft Report**

Thank you for the opportunity to comment on the Draft Report and the findings and recommendations made in it.
In this submission we do not address each Recommendation or Finding but limit our comments to areas of most concern. We would be pleased to discuss any aspect of our submission or the Draft Report with you.

## Chapter 2 – Assessing the IP system – an analytical framework

We appreciate that the Commission applies an economic framework for analysing the IP system. We wish to reiterate the observations made in our submission on the Issues Paper, which we consider continue to be relevant.

### Further observations on "additionality".

In section 2.3 of the Draft Report the concept of "additionality" is defined in terms of "the creation of genuinely new and valuable IP, which would not have occurred otherwise". This definition is given in the context of the statement that "[a]n IP system is effective it if promotes the creation of" such "additional" IP. Although the concept of additionality is superficially clear from this description, we propose a clarification that we consider would be useful to those policy areas that draw on the concept of "additionality" discussed in various subsequent sections of the Draft Report.

It is not entirely clear whether the Commission intends the concept of additionality to be limited to: (a) ensuring inventions are developed that would not have occurred but for the patent system; or (b) ensuring inventions are developed *or commercialised* that would not have occurred but for the patent system. The latter interpretation (b) seems to apply in section 6.2 of the Draft Report, whereas some other sections refer to the concept of additionality in a possibly narrower way, more along the lines of (a).

We consider that the concept of "additional IP", i.e. that which would not have occurred but for the IP protection, should be broad enough to embrace the innovation that the IP enables, and not be limited to the generation of the IP itself (at least in the case of patents for inventions). In other words, with reference to a particular patent for an invention, the question should not be *limited* to whether that invention would have been made in the absence of the availability of a patent for the invention, but rather, whether the lineage of innovation including that invention, and including innovation downstream from that invention, would have been made in the absence of the patent.

This distinction is important, because it recognises and values the role of the patent system in facilitating investment in a larger development process (i.e. beyond the invention itself) that is often necessary to achieve impact from the invention, i.e. to achieve genuine innovation. The exclusive rights provided by the patent may encourage and enable investment in further development of the invention to enable the IP to be successfully implemented. It is this context of stimulating the usefulness of the invention in downstream innovation that the patent system seeks to achieve. The context for additionality which is important for practical purposes should therefore include use of patents and the generation of further innovative outcomes, not simply generation of an isolated invention. Accordingly, we consider interpretation (a) above to be too narrow for practical purposes.

To take an arbitrary example to illustrate, consider the invention of a novel active molecule designed to be effective in treating a particular disease condition. In order to develop that initial invention into a medication, significant further development and investment is required, along a well established development pathway, for example to assess toxicity, determine a suitable delivery method, determine suitable dosage ranges etc. In this example, a patent for the original invention may be vital to secure investment in the downstream development of the initial invention necessary to achieve impact – even if a patent for the original invention may not have actually been necessary to achieve the initial invention itself.

This example is not intended to be limited in any way to pharmaceuticals – it simply illustrates a feature of innovation common to many fields, namely that an initial invention typically requires significant downstream investment in development to enable practical utilisation of the invention.

## Chapters 4 and 5 - Copyright

CSIRO has made submissions to the ALRC in connection with aspects of copyright which remain relevant to the Commission's review.

## Chapter 6 – The patent system: focussing on the fundamentals

### 6.4 Introducing an objects clause

CSIRO considers the Commission's proposed objects clause in the Patents Act is likely to introduce uncertainty and cause disputes, and may not be TRIPS compliant. Consideration of the objects in the form proposed by the Commission is problematic in our view because it potentially involves subjective, value-laden considerations, rather than objective criteria. Irrespective of whether the proposed objects would be desirable if one were freshly designing a patent system, the existing patent validity criteria are not well-aligned with the proposed objects.

In particular, the proposal that the Commissioner of Patents and the Courts must have regard to the objects clause when making a decision in relation to a patent or a patent application would appear to effectively introduce an additional potential ground of invalidity. If a patent or patent application otherwise satisfied the validity criteria, then it is conceivable (indeed it appears to be the intention), that consideration of the objects clause could lead to the patent or application being held invalid. The Commission itself noted the following in explaining why it chose not to propose some form of specific test for additionality, which we consider to be equally applicable to the proposal of adding an objects clause to which decision makers must have regard: "A new test may also contravene the TRIPS Agreement, which appears to mandate novelty, usefulness and the inventive step as the sole criteria (other than subject matter eligibility) for granting a patent."

### 6.6 Observations on the experimental use exemption

In section 6.6 of the Draft Report, under the heading "Are exemptions from infringement fit for purpose?", the Commission invites information in relation to the scope of the experimental use exemption to patent infringement.

In CSIRO's July 2009 submission to the IP Australia's consultation process, we introduced our approach to the issue of an experimental use exemption as follows:

1. Australia and the world face many pressing challenges where science and technology are needed and expected to develop solutions. Current areas of high public awareness include research on the environment, climate, energy, water, and health. CSIRO considers that Australian law and policy should encourage carrying out scientific research and acquiring knowledge, and should accordingly reduce barriers to conducting research as far as possible.
2 CSIRO supports a broad research exemption to patent infringement as an important measure to reduce barriers to research. CSIRO also recognises that appropriate protection must be maintained for patented research tools, and that the scope of any proposed research exemption must ensure compliance with Australia's obligations under the TRIPS Agreement.
3. CSIRO considers that Australian law and policy should seek to make Australia a favourable jurisdiction for research investment. Accordingly we consider that Australia should not adopt an exemption that is narrower than: (i) the exemptions of any other major patent jurisdictions; or (ii) the full scope of exemption permitted by the TRIPS Agreement.

In CSIRO's further submission to IP Australia of May 2010 we undertook a detailed analysis of the relationship between the requirements of the TRIPS Agreement and the potential scope of TRIPS compliant experimental use exemptions. In paragraphs 6.17 to 6.23 in particular, we argued that there is scope within TRIPS for a broader exemption to patent infringement for experimental uses of patented technologies than is now permitted by the experimental use exemption in section 119C of the Patents Act.

In particular, we argued than an exemption based on the architecture of a broad research and experimental use exemption, with an exception from the exemption for research tools, could be TRIPS compliant. Our 2010 submission considers some possible options for the scope of a research tools exception to conduct otherwise exempted, which could ensure for example that: (a) the sale of products protected by research tool patents is not exempted from infringement; but that (b) making and using a product, or using a process, protected by research tool patents could be exempted if it is done predominantly for experimental or research purposes.

We understand that our earlier submissions to IP Australia referred to above are publicly available but would be pleased to make them available to the Commission directly if requested.

**Chapter 8 – Business method and software patents**

CSIRO considers that it is important to ensure that patents continue to be available for software embedded in technology inventions. We consider this important from the perspective of TRIPS compliance and from first principles in a technology neutral policy analysis.

Technology inventions that utilise software to function represent an economically important field of technology which is expected to continue to grow as more areas

become amenable to digitisation. While exclusion from patentability of software "as such" could likely be justified under TRIPS as being outside the concept of an "invention" for which patent protection must be available, in our view the same cannot be said for inventions with embedded software.

From first principles, and without regard to TRIPS, inventions that utilise software can be economically important and socially valuable, as in other fields of technology, and are no less deserving of ensuring investment than other areas simply because they include a software component. For example, consider medical imaging technology. These methods operate on data streams obtained from real hardware (e.g. image collection devices such as X-ray or MRI machines) to produce image output that can enable a medical practitioner to visualise parts of the human body for diagnostic purposes or to guide surgery or other medical procedures.

CSIRO considers that it is important that patents continue to be available for software embedded in technology inventions.

## Chapter 12 - Plant Breeders' Rights

> **Draft Recommendation 12.1**
> The Australian Government should proceed without delay to implement the Advisory Council on Intellectual Property 2010 recommendation to amend the Plant Breeder's Rights Act 1994 (Cth) to enable essentially derived variety declarations to be made in respect of any variety.

In general CSIRO agrees with this proposal. The Commission is seeking additional information in connection with PBRs and new patented varieties. In principle CSIRO considers that a breeder should be free to determine what IP protection to seek for a new plant variety.

While new technologies will potentially allow a new trait to be introduced into an existing cultivar, it is not a fast process. It generally takes years to test for the effectiveness of the new trait and to bulk up commercial quantities of an improved line. This enables the owner of the original variety to generate returns from investment before the improved line emerges. As the Commission has noted the market life of new varieties is limited. For cereals, the market life is typically about 9 years and it is unlikely that new technology will allow an improved line to be ready for market sooner than about 6 years.

Where a transgene or edited gene trait is added directly into a PBR variety and no crosses are made, then a licence with the PBR owner may be appropriate with a negotiation resulting in a proportionate sharing of return on investment. We do note that often access to PBR varieties is subject to contractual terms under material transfer agreements that limit what can be done, providing the PBR variety owner with rights under that contract that may not be available under the PBR regime. There is no reason, however, to undermine the patent protection that the owner of the new variety should have and be entitled to seek to obtain a return from the investment in the resulting patented variety. If however crosses are made to a different cultivar and the resulting variety is patented, then there would be no need to negotiate a licence for breeding. It takes years, and significant investment, to create a good variety after a

cross is made, that period permitting the owner of the original variety to generate returns from its investment in the original PBR variety.

**Chapter 14 – Intellectual Property Rights and Competition**

As CSIRO stated in its November 2014 submission to the Harper review, if the section 51(3) exemption is to be repealed then we would wish to see suitable compensating mechanisms put in place to ensure that technology licence transactions are not rendered more difficult, time consuming and costly. In this regard we consider that providing detailed guidance materials for technology licensing transactions and provision of a legal "safe harbour" (in which compliance with published criteria would provide an exemption from, or deemed compliance with, the law prohibiting anticompetitive agreements) should ideally be used.

CSIRO supports the recommendation that if the section 51(3) exemption were to be repealed, then the per se prohibitions should be repealed or made subject to a competition test.

**Chapter 15 - IP and Public Institutions**

Chapter 15 of the Draft Report discusses the IP regime as it might apply to public institutions such as CSIRO. The chapter contains one recommendation:

> **Draft Recommendation 15.1**
> All Australian, and State and Territory Governments should implement an open access policy for publicly-funded research. The policy should provide free access through an open access repository for all publications funded by governments, directly or through university funding, within 12 months of publication. The policy should minimise exemptions.
>
> The Australian Government should seek to establish the same policy for international agencies to which it is a contributory funder, but which still charge for their publications, such as the Organisation for Economic Cooperation and Development.

Before discussing the Draft Recommendation in more detail, we note that, as stated in the Draft Report, research is not a standardised activity and will be carried out in many ways and for various reasons[1]. Often research is carried out with other entities, both public and private, local and international. Despite the Commission's somewhat confusing comments on a stated rationale of the IP system being its capacity to be an effective tool for supporting innovation and creativity,[2] as we noted in our comments on the Issues Paper, in CSIRO's experience, securing appropriate IP protection for research outcomes is a vital tool for technology transfer. Research is often commenced with a view to developing subject matter able to be protected by those rights in order to support later technology transfer activities. We maintain this position.

Technology transfer is one of CSIRO's primary functions.[3] The Government's expectations of CSIRO are that it carry out world class research and that it actively

[1] Draft Report p.401.
[2] Draft Report, section 3.1 p.74. Whatever the origins of the IP system (which are varied) it is the current and potential role of IP in the innovation system that is important.
[3] ***Science and Industry Research Act*** 1949, s9.

collaborate with other research institutions and particularly with industry in translating research into commercial outcomes and building internationally competitive businesses.[4] As we also commented in our submission on the Issues Paper, IP does indeed provide incentive to facilitate the development of research into a useful product. It seems to us that public moneys may therefore be provided for various purposes. If it is intended that public money be used to develop technologies to be commercialised in some way, for example, to develop industries and bring other social benefits, then whether all research outcomes should be published or not has to be a decision available to the research institution. Even where publications are the intended outcome of research, whether all material should be published is again an issue for the researchers involved, assuming all ethical considerations are taken into account. It is not appropriate that publication of incomplete, inaccurate or potentially misleading information be mandated.

In discussion leading to Draft Recommendation 15.1, the Commission refers to "government providers of information" providing knowledge content for free, and noting that "there is not yet a comprehensive policy covering all publicly-funded research. For example, CSIRO Publishing provides open access to its publications, but has author pays arrangements." [5]

In fact CSIRO Publishing is a business unit of CSIRO and operates as a publisher of scholarly journals and books authored by writers from a variety of national and international organisations[6]. It is not the publisher of all CSIRO research content. Notwithstanding this, much CSIRO research output is made freely available through CSIRO's website. [7]

In considering the proposed recommendation, we have presumed from the context of the discussion that the Commission is intending that such a policy would apply to peer reviewed publications in scholarly journals.[8]
In principle and assuming the presumption as to the type of publication concerned is correct, this is a reasonable proposal and one which CSIRO would support provided costs of implementing it were not excessive[9]. It is related to previous government initiatives seeking to make 'public sector information', such as the information from the ABS and the Commission, freely available.

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[4] Statement of Expectations, February 2015 http://www.csiro.au/en/About/Leadership-governance/Minister-and-Board/Statement-of-Expectations
[5] Draft Report at p.408.
[6] In relation to such scholarly materials, CSIRO Publishing operates so as to generate a return to cover its costs of publishing material, much of which is written by non-CSIRO authors and some of which is made available on an open access basis. In line with most other scholarly publishers, CSIRO Publishing provides the author with certain reuse rights, including deposit in repositories of pre published versions of journal articles. Where an author or an author's institution seeks open access (i.e published content being made available on a creative commons type licence from publication) in these scholarly journals, payment is sought from the author. In many cases, both paper and digital copies of journals are sought by users. In each case, the publication process is similar and, as the Commission has noted, is not cost free.
[7] For example, CSIRO repositories for publications (ePublish) and the Data Access Portal, as well as the Atlas of Living Australia.
[8] This would be in line with the publications covered by the NHMRC policy, for example.
[9] For example, publisher charges; repository establishment and management costs.

A broader blanket obligation that required publication of all research outcomes where any public funding had been involved would not be appropriate, including for the reasons set out above in the discussion of CSIRO's functions.
A blanket obligation would be a blunt instrument indeed, failing to take into account valid considerations for determining whether and if so when and what to publish, and may discourage private entities from collaborating with public institutions in the conduct of research or its commercialisation.

Given the nature of CSIRO's research and commercial activities and the various relationships it enters into in seeking to meet its obligations,[10] not all research with which it is involved can be *completely* classified as fully publicly funded research. A general and broad obligation would operate differently to a situation where funding for particular projects is subject to an open access requirement (e.g. where there is funding from a body with mandated open access policies such as the ARC or the NHMRC). In that case, there is potential to choose whether to conduct the research under the terms for that funding. A broad policy may decrease incentive for collaboration with private entities.

Open access policies for publications relating to publicly funded research need to accommodate the realities of research, publishing and peer review and commercialisation of research outcomes.
For example:

- Particularly where there are commercial, privacy, confidentiality, security and cultural or environmental sensitivity[11] and IP considerations, compulsory publication of outcomes may conflict with those obligations and with the planned impact pathway for the research, whether by CSIRO or a third party. In some cases, this means publication is delayed. In other cases, there may be no publication or publication of only some outcomes.
- 'Open access' implies there would be some licence such as a creative commons licence attached to published material. Where third party material is used in research or where copyright is assigned to a publisher, other licensing or limited use obligations may be needed in order to accommodate these rights. Negotiating for rights to permit free licensing can be very difficult, time consuming and costly. If the intention is that information be disseminated through the ready access of material, then 'open access' need not necessarily require any more than 'free to view'.
- Mandated publication within particular absolute timeframes risks jeopardising research to develop and refine inventions and ensure patent protection. For this reason, CSIRO supports open access policies for publicly funded research in which the time requirements for providing free access are measured from the date of publication, where the research organisation is entitled to determine when the material will be published.
- Mandated publication within particular timeframes may be difficult where, for example, peer review suggests additional work is required to be carried out before a publication of sufficient quality is available.

[10] See the Statement of Expectations referred to above.
[11] Environmental sensitivity may result in a need to not publish locations of endangered species, for example.

- Where publication is to be in a journal, then open access with a free licence can be obtained with most publishers through payment which adds to the cost of research and dissemination of results.
    - While the observation that there may ultimately be quality, free journals is noted, the need to have properly managed peer review is an important factor in deciding to publish in 'traditional' journals. One role of a publisher is to organise published material to enhance discoverability of material – just placing material on the internet or into a repository (the development and management of which is also not cost free) is no guarantee of it being found. This differentiates research outcomes from 'public sector information' where it is generally obvious where information on, say, Australian census data, can be found.
    - Similarly, placing material online and inviting comment and review is no guarantee of proper peer review or even informed commentary.

The Commission makes observations about the circumstances in which inventions developed by publicly funded research organisations ought to be patented and CSIRO agrees that the IP system ought not to be used to predetermine an outcome. The results of research are never clear from the outset or guaranteed and how best to achieve the greatest public benefit from those results requires assessment on a case by case basis and may evolve over time as further research is carried out, for example. Effective and active IP management of inventions means that decisions on patenting can be made and reassessed regularly. It is not unusual for decisions to be made to abandon a patent or a patent application where it turns out that the invention is not able to be readily exploited. That normally means that the information about the invention is publicly available either through a published patent specification or a published paper or report.

CSIRO supports the Commission's preliminary view that universities and public research agencies should not be mandated to provide open access to their inventions, and that institutions should have flexibility to decide how to make inventions available to the public. In particular, as stated above, one of CSIRO's primary functions is to facilitate the application or utilisation of the results of scientific research. CSIRO considers that patent protection is in many circumstances a vital tool for enabling investment in further development of inventions, including commercialisation, and to mandate open access to CSIRO's inventions would undermine CSIRO's capacity to fulfil this key statutory function. CSIRO also supports the Commission's preliminary view that institutional ownership remains preferable to government ownership or "professor privilege" in relation to ownership of publicly funded research, and from CSIRO's perspective, is an essential component of its capacity to fulfil key statutory functions.