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Open Source, Open Science, Open Society

Public Support for Science and Innovation Productivity Commission

CAMBIA Background

CAMBIA is an international, independent non-profit research institute based in Canberra. For more than a decade, CAMBIA has been creating new enabling tools to foster innovation and a spirit of collaboration in the life sciences. We are applying open source principles to enhance transparency, accessibility and capability to use patented technology in the life sciences for the benefit of humanity.

We would like to comment specifically on the Commission's mandate with respect to:

- Identifying impediments to the effective functioning of Australia's innovation system and scope for improvements
- Evaluating the decision-making principles and programme design elements that guide the allocation of funding between and within the different components of Australia's innovation system

Scientific innovation and freedom to operate

Much of modern science, including biotechnology and other high tech industries, currently aims to use intellectual property regimes in order to establish rights and generate revenues by applying for the award of a limited term monopoly in exchange for a full written disclosure of new inventions. If granted, a standard utility patent confers "the right to exclude others from making, using, or selling the invention," for 20 years from the date of filing.

However, developing useful products often requires many different technologies and techniques. Having a patent over a technology guarantees the right to exclude others from using the technology, but not the right to use the technology, which may be subject to other, more broad patents constraining it. Patent claims can be overlapping and unclear, with some only being clarified after legal challenges requiring years and large expenditures. A complex thicket of proprietary claims exists in many fields, for example biotechnology, that limits freedom to operate of both public and private entities. . A famous example is GoldenRice™, a form of rice genetically engineered to provide a Vitamin A precursor, for which over 70

patented technologies belonging to 32 different entities were used (Kryder *et al*. 2000). A more recent study by the University of Iowa similarly found over 70 patents being infringed by technologies being used in a research laboratory (Wysocki 2004) and there are many other examples emerging (Scott, 2005 and Cukier, 2006).

In order to commercialise any discovery, it is critical to understand the legal landscape as well as obtain licensing from each patent holder. If even one entity refuses to license the relevant technology, it is impossible to provide the product in a market where the patents are in force.

For universities and non-profits who knowingly or unknowingly use patented technologies in their research (*not* commercialisation), the immediate consequences are apparently slight, as patent holders tend not to sue individual researchers or educational institutions, knowing the repercussions in terms of public relations would be potentially high and the financial gain low. Thus, many researchers are unaware of the IP restrictions that may exist in the areas of technology they investigate, and don't feel a need to know about them.

However the long-term consequences to the delivery of research that benefits the economy are much more significant. Funders of research, investors and lenders may be increasingly understandably reluctant to invest in research projects that, while interesting, may never be delivered to the public, even for humanitarian uses, because any scale-up or commercial-scale implementation can be prevented by any of multiple patent-holders whose patents were infringed during the research phase.

Furthermore, injunctions can stop or delay exports into any market for products that embody technologies patented in that market, even if they are not patented in the region where the agricultural products were grown, as exporters of agricultural crops into Europe have unfortunately found. Similar cases have prevented imports of software and pharmaceuticals into the US market. Challenging patents in Europe and the US is a costly process that few Australian businesses may be in a position to endure.

Thus, IP regimes are becoming a constraint on the delivery of the fruits of non-profit research even in the developed world, and the importance of understanding freedom to operate is growing. As a resource-rich country highly dependent on exports to countries with strong IP protection but making only modest investment in domestic R&D, Australia is already seeing sectors of its industry suffering (Nottenburg, *et al.*, 2002).

If the goal of publicly-funded research is ultimately to deliver products or provide benefits to people, freedom to operate is critical. Without a clear understanding of potential constraints to product development, resources are too frequently channeled to projects that can never reach the market. Funders – or recipients – must do their homework in order to get the most out of their investments. It is estimated that underexploitation of technical information (an estimated 80% of which is published in patent documentation and nowhere else) costs European industry alone $20 billion each year – simply because the inability to access relevant patent information results in duplication of effort or the creation of products for which patents are

ineffective because of prior invention by others (Editorial, *Nature Biotechnology* 2006).

New approaches to open innovation

Many barriers to delivery are formed by fear, uncertainty and doubt about the availability of licenses, and licensing practices that result in exclusive control by entities that are not in the best position to exploit the technology for the good of the public or the economy. Non-exclusive licensing practices and new practices that promote wider availability of the means to improve technology promote healthy pre-competitive cooperation and a healthy economy. The open source movement in the software industry has brought credible evidence to support those who assert that tight control over the means to innovate is not a necessary prerequisite for innovation. Using "open source" licensing principles (anyone can improve and use the technology for making a profit, as long as they do not prevent others from using it), many small and medium companies – and some as large as IBM – are making formidable profits by selling services based on open software development. In 2003, IBM took in US$2 billion in revenues from services and innovation based on unpatented Linux code, more than double the revenues earned from outlicensing its own patents. (Lyons, DiCarlo, 2004). Technology advances allow for creative programmers to contribute their expertise from all over the world, and expert communities are collaborating and innovating together on hundreds of projects.

In this model any motivated individual, whether in for-profit or non-profit enterprises, can contribute ideas to a pool available to many entities without any entity having the ability to hijack the whole. While in many areas of research, e.g. in the life sciences, research and development timelines are much longer than in the IT world, the Biological Open Source Initiative (BIOS) has developed open source licenses and materials transfer agreements that can apply to patented and patentable technology, making inroads toward resonant goals. Processes in these industries stand to benefit even more strongly from a wide corps of improvers, testers and implementers working in different environments. The objective is to incentivise and coalesce a creative process of solving problems locally with technology accessed globally (Connett-Porceddu and Jefferson, 2004).

Opportunities for the Future

In order to make wise investments, it is critical to ensure that there are no barriers to delivering research results. It is evident that the national research priorities aim to deliver results to the Australian people, and this element of public good can be achieved only with thoughtful consideration not only of scientific and social frameworks, but also legal frameworks. This is by definition a moving target, as patent claims are continually issued, challenged, denied and withdrawn. Clearly, better information on patents, lower cost ways to obtain and update information on freedom to operate, and new alternatives in licensing practices can all contribute very substantially to wise investments in research that will deliver for the Australian people.

The Productivity Commission Issues Paper invites issues and answers to a number of questions, and the following are some we are in a position to

comment on:

1. topics for case studies which could illustrate impediments to innovation:
    - Using example key patented technologies from the agricultural world, CAMBIA has developed a well-respected series of "technology landscapes", freedom to operate analyses in researcher-friendly terminology defining tools and techniques that are widely used in research but only infrequently used to create products because of the multitude of patent holders: http://www.bios.net/daisy/patentlens/tech_landscapes.html

    - Many research projects would benefit by doing such freedom-to-operate analysis early in the process and updating it throughout the research and as partner choice and investment is being considered, but the skill required is high and the cost of updating the analysis means that it is often delayed (Cukier 2006). In addition to its experience in creating the example landscapes mentioned above, CAMBIA is now developing tools that reduce the cost and enable greater update frequency through annotatability and RSS feeds: http://www.patentlens.net.

2. social and environmental impacts of public support for science
    - The current impacts of public support will be much less than desired if funding goes into research that cannot have deliverable outcomes. Whether private business investments or public benefit and humanitarian investments, good investments require good information in order to reach deliverable outcomes. As outlined above, patent information is often important and can be very useful, but often left untapped by researchers.Research funders could and should demand analysis of delivery constraints, such as freedom to operate, at the inception and during execution of research projects.

    - Increasing patent transparency will be an important advantage to aid governments make appropriate investments that can deliver social and environmental benefits to society (Merrill *et al.* 2004). Currently patent information for Australia is fragmented and difficult to access, and many different jurisdictions should be accessed for good analysis of technologies that have any international prospects or involvement (Connett-Porceddu *et al*. 2005). To address this need, CAMBIA has developed tools to promote patent transparency through the Patent Lens, one of the world's largest free, full-text integrated patent databases allowing searches of all US and European and many Australian patents, and US and world patent applications.

    - There are also significant opportunities to reform the patent system in order to curb abuses and promote innovation (see Jaffe and Lerner, 2004, although it is a somewhat US-centric view of patent reform possibilities). Study of reform opportunities particular to Australia should be undertaken by Australian-based institutes familiar with both Trilateral (USPTO, EPO, JPO) and Australian patent data and patent practice. Disallowing reach-through claims, significantly raising the standards of inventive step and utility for patenting enabling tools and biological sequences, taking steps to implement

the Development Agenda (http://www.eff.org/IP/WIPO/dev_agenda/) for patenting practices, and reform of divisional and continuation practice would all be supportive of innovation.

- Both the USPTO and EPO are considering experiments with open web-based peer review of patent applications by the general public in order to enhance patent quality by enhancing the chances that patent examiners are assisted in finding prior examples of inventions and flaws in enablement. Such a system could work very well in the Australian innovation climate, not only for patent applications but also for issued patents, to unearth information about license availability, overseas challenges to related patents, In CAMBIA's Patent Lens, a third-party commentary feature is planned to allow public submissions on patents and prior art, which should help to enhance the information available to patent examiners, innovators looking for room to invent, and prospective licensees.

3. Which countries are most relevant for analysis in Australia?

- Some have looked at the impact of the Bayh-Dole Act in the US as a model for Australia. The Bayh-Dole Act governs inventions created with federal funds, and grants a right to ownership to the research institution subject to a number of obligations. While the original goal was to provide an incentive for improved technology transfer, in more lucrative areas for patenting, universities have entered into competition with research-performing companies, which has driven up costs and slowed the pace of research in universities and companies alike (Mowery, *et al.*, 2004). There is widespread misunderstanding of what the law actually requires and how it was intended to spur innovation., a topic deserving of some study.

- The manner in which the Bayh-Dole Act has been implemented particularly by universities and public research institutions is under increasing criticism, and many are encouraging a rethinking of this law in the US (Boettiger and Bennett, 2006), which suggests some ways in which Australia might do better than the U.S. has done. In Europe, Brazil, India and South Africa, consideration is being given to variations in which inventors rather than universities own technology, and open source licensing modes are encouraged.

4. What benchmarks are currently used to assess outcomes, and what gaps are there?

- Patent applications or the number of patents issued are often used as a benchmark for research productivity, but much valuable research is not patentable or would be better disseminated without patenting, so whether a patent application is made has nothing to do with productivity or research quality. The high cost of filing and prosecuting a patent means that institutions are not on a level playing field, and many suffer by this policy. In 2002, North American universities spent over US$200 million--more than five times the amount spent in 1991. Despite university investments in technology transfer offices and patent attorneys in recent years, roughly a third of new discoveries and more than half of all university licensing income derived from just ten universities (Leaf, 2005) while all of the hundreds

of other US-based universities are actually losing money on the costs of patenting new technologies and seeking licensees. The situation is comparable in Australia; only a very small percentage of institutions, if any, are actually bringing in patent revenues that outstrip the costs of patenting and seeking licenses. Even CSIRO is not successful in exceeding patent litigation and prosecution costs with licensing revenues.

- Online journals such as PLOS and forums for online collaborative development of research work, such as sourceforge.net and bioforge.net, are increasingly important for rapid dissemination of research that may not be patentable or publishable in traditional scholarly journals, but which may nonetheless be valuable, including repeating results in different environments, descriptions of failed experiments that would be a waste to repeat, common-language descriptions of research, etc. In an online community of researchers, there are new opportunities for fairer and wider peer review that continues even after documents are published, unlike the static contributions in journals. Credibility point systems are being developed in many such online communities to rank contributions or comments – those who provide the most useful and credible contributions gain "points", translating into a better reputation as trustworthy "experts" within the community, as well as higher attention-getting via an increased ranking for relevant future contributions. CAMBIA has identified a goal of studying incentive structures and systems underlying collaborative communities, with the objective to identify, develop and possibly integrate appropriate reputation algorithms in our technology platforms in order to facilitate richer discussions and better incubation conditions for relevant ideas for scientific innovation. Any reputation management algorithm must involve thoughtful sociology and must anticipate the potential misuse of a voting paradigm through gaming or self-referencing (this often happens with conventional publication references and citations). It should also take advantage of the technological properties of a digital platform, and implement a new level of transparency, lowering transaction costs for contributors and critics, and signal importance to the users rather than mere quality control, *i.e.* allowing the users to feed back "How useful is this to you?"

- For both publications and patent applications, as well as other forms of research dissemination, more useful indicators than numbers might be metrics directly related to the number of products that reach the general public using a technology described in the publication or patent application, or number of people positively affected by implementation of the research findings. Other metrics fail to keep in perspective the public good aspect of the research that is evidently intended in the way the national priorities have been defined.

5. Institutional impediments that may cause innovation system failures.

- In #1 above we discussed technology landscapes as a way of constructively approaching patent "thickets" which block both development of new innovation and delivery of existing innovation to people who need it.

- We also discussed the critical need for a level of patent transparency and integration of patent datasets for multi-jurisdication searching that is not currently provided by IP Australia for the benefit of Australian innovators. Without a clear understanding of patent landscapes, funding cannot be allocated efficiently to the research that has the best chance at solving problems on the ground.

- Finally, studies and reform of licensing practices and policies for other types of contracts handling IP are needed. CSIRO's current difficulties with severe and costly US court setbacks associated with its licensing practice (Intel, Corporation and Dell, Inc. vs CSIRO and Microsoft, Hewlett-Packard, and Netgear Inc. vs. CSIRO 2006) illustrate some pitfalls of traditional approaches to licensing in the increasingly globalised world of trade. There is also increasing concern about the way that Materials Transfer Agreements are being used to restrict the flow of materials essential to research, in the absence of or for terms exploitatively longer than legitimate patent rights. Both the Convention on Biological Diversity and the World Health Organization have issued reports in 2006 calling for new approaches to IP rights, including open source licensing for access and benefits sharing and for maintaining wide public access to research tools (CBD, 2006, and WHO, 2006). Open source licenses for new technologies and simple open source-compliant MTAs are now being devised by CAMBIA's BiOS Initiative, and we are keen to see better understanding of the conditions under which germplasm is transferred, less use of "permanent" MTAS, and enhanced explanations available to tech transfer offices of the alternatives available and the high value of greater flexibility in licensing practices.

To supmmarise with the most important recommendations among the above to approach greater sustainability of the fruits of Australian research, addressing the issues mentioned above and the underlying causes in the Australian context:

1. Requiring all federally-funded research projects to complete a freedom to operate study before research begins
2. Fostering greater consistency and accessibility to researchers of the information available on patents and patent applications filed in Australia and in market jurisdictions important to Australia
3. Evaluating alternatives to traditional patenting practices with the goal of enhancing public good (e.g., open source type licenses, BiOS-compliant MTAs)

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This submission was prepared by Carla Boeckman, CAMBIA's Director of Alliances and Development, previously of the World Economic Forum and the US National Academy of Sciences; Rachel Parry, CAMBIA's Communications Director, previously of the International Institute for Sustainable Development, and myself (biography below), Please contact any of us if CAMBIA can be of further support to the Productivity Commission.

Best regards,

Dr Marie Connett-Porceddu
Deputy Chief Executive Officer
CAMBIA and the BiOS Initiative

Biography

Marie Connett-Porceddu, M.B.A. (*USC*), Ph.D. (*Cornell*) joined CAMBIA after more than a decade in the primary production private sector. She leads the IT and IP analysis team that runs the Patent Lens, and she coordinated the development of the first BiOS-compliant license, subsequent variation and a BiOS-compliant MTA, the prototype BioForge, and negotiations with industry bodies, academic technology transfer offices, and non-profits for adoption of Biological Open Source.

Prior to her appointment, Marie had been working in industry for more than ten years as a research manager and in management of intellectual property, and had five years of university faculty experience (she is currently an Adjunct Professor of Charles Sturt University). In industry she led several research groups and is an inventor on multiple patents and families of patent applications in plant biotechnology and genomics.

Marie's Cornell University Ph.D. in Plant Sciences followed two BA (Hons), in Biology and in Modern Languages and Literatures. A tri-national citizen of New Zealand, USA and Italy, she can use several languages fluently. She is a registered patent agent with the USPTO, earned a professional M.B.A. from USC, and has entrepreneurial experience as a business analyst, consulting on business plans and value capture models for small and large enterprises internationally.

About CAMBIA

CAMBIA advocates a fair and equitable innovation system and through its BiOS (Biological Innovation for Open Society) Initiative has created a suite of tools to further this goal.

The Patent Lens is a global resource for increasing patent transparency. Based on one of the world's largest free, full-text integrated patent databases, the Patent Lens also provides technical landscapes on key biological enabling technologies, patent tutorials and information on patent policies. The Patent Lens currently serves up over 5.5 million patents and patent applications from the USPTO, EPO, WIPO and IP Australia. The USPTO collection has recently been expanded to cover all categories, not just the life sciences. The Patent Lens also provides legal status and related patents data from over 70 patent offices, extracted from the INPADOC database.

A series of BiOS-compliant licenses are designed to enable sharing of a dynamic, continually growing capability to use and improve technology within a "protected commons". BiOS licenses are legally binding contracts that can replace traditional, inflexible licenses, and stipulate that licensees share improvements and biosafety data, but gain benefits from others' improvements and data in a continually growing pool. As well, licensees may not stop other licensees from using the technology to develop different products, but neither will they be stopped by other licensees, so they obtain some protection against barriers to freedom to operate.

CAMBIA has seeded the first protected commons with its own technologies including GUS and GUSPlus™, the Agrobacterium-independent TransBacter™ plant transformation system published in Nature in 2005, a solid state genotyping technology already used in many agricultural species, and core medical technologies associated with cancer and stem-cell research.

In order to facilitate collaboration among BiOS licensees and other interested parties, CAMBIA has prototyped a collaboration platform that uses the Internet to serve up tools from different geographic locations and time zones, the BioForge. The BioForge is an Internet-based distributive community, to allow scientists and other innovators in diverse locations to work with each other, and with those who can apply and use their research.

FURTHER INFORMATION
www.cambia.org
www.bios.net
www.patentlens.net
www.bioforge.net