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Ms Naomi Bleeser
Committee Secretary
Community Affairs References Committee
(Genes Inquiry)
Parliament House
Canberra ACT 2600

8 April 2010

Dear Ms Bleeser

I am writing in response to your letter of 11 March 2010, in which you asked IP Australia to consider the submission filed by Senator Heffernan and to respond to its contents and recommendations. I thank the Committee for giving IP Australia this opportunity to comment.

While we do not think that it is appropriate for IP Australia to address the specific recommendations we do offer some observations by way of clarifying and commenting on specific issues raised, which may assist the Committee in its deliberations on the recommendations.

Background Considerations

In Australia, and in all but a few other countries, patent protection is available for biological material, including isolated nucleic acids and proteins and/or their uses, so long as the relevant patentability requirements are met. Patents are not granted over biological or genetic material as it exists in its natural state or *in situ* in a human, animal, plant or any other organism.

Inventions relating to isolated nucleic acids and isolated proteins are assessed against patentability criteria applicable to all inventions regardless of technology type.
All inventions are assessed as to whether they represent a manner of manufacture, are novel, inventive and useful, as well as on the requirement that the description of the invention meets the tests of full description and fair basis. The joint submission from the Department of Innovation, Industry, Science and Research and IP Australia to the Senate Inquiry provides a comprehensive discussion of these patentability criteria (see paragraphs 4.7- 4.8). The Committee's attention is particularly drawn to the discussion on Patentable Subject Matter and Discovery versus Invention (see paragraphs 4.11-4.19 and 4.27-4.31).

Australian History of Patenting Biological Materials and Products of Nature

IP Australia provided the Committee with copies of two patents reflecting Australia's long standing history of granting patents over biological material isolated or extracted from natural sources, so long as the material has a practical use. Senator Heffernan's submission indicates that the compositions and products claimed in these patents are not analogous to isolated nucleic acid sequences or isolated proteins and therefore do

not support IP Australia's practice of granting patents for isolated genetic material (see page 65).

IP Australia considers that the examples unequivocally demonstrate the patenting of useful products and compositions, extracted or isolated from nature but which are different in kind and form from matter as it exists in nature.

Senator Heffernan's submission notes that in 1919 a new provision[1] was introduced into the UK Patents Act which made chemicals, food and medicines unpatentable (see page 46). This provision was removed in the 1949 Act and a new provision section 4(7) added. Section 4(7) stated that a claim for a new substance shall be construed as not extending to that substance when found in nature. The Senator suggests that similar care must be taken to ensure that Australian patent law does not allow the patenting of naturally occurring products.

The Australian *Patents Act 1952* followed the 1919 UK Act to some extent by enabling applications to be refused on the grounds that an invention was a food or medicine that was a mere mixture of known ingredients, or a process of producing such a substance by mere admixture.[2]

By the mid-20th century, the test for patentable subject matter in Australia consisted of a patchwork of rules and precedents that had been developed for specific subjects. As discussed in IP Australia's joint submission to the Committee, in 1959 the Australian High Court produced a watershed decision on patentable subject matter in *National Research and Development Corporation v Commissioner of Patents*[3] (*NRDC*). The High Court provided a set of guiding principles and emphasised the broad and evolving scope of the manner of manufacture test.

One of the *NRDC* principles is that, to be patentable, an invention must give rise to an artificially created state of affairs. As discussed in IP Australia's joint submission to the Committee (see paragraphs 4.15-4.19), chemical compounds such as gene sequences that are isolated from nature satisfy this principle. Current Australian law therefore accords with the approach taken by section 4(7) of the 1949 UK Act and how that was interpreted by the UK Patent Office. In any case, IP Australia notes that current UK legislation no longer includes such a provision. The 1977 UK Act states that an invention is new if it does not form part of the 'state of the art'[4] and that a discovery is not an invention and therefore not patentable.[5]

The Advisory Council on Intellectual Property (ACIP) is currently reviewing the test for patentable subject matter and expects to provide a final report to the Government around the middle of this year.

Ranks Hovis McDougall Limited

The Senator's submission refers to *Ranks Hovis McDougall Limited's Application*[6] *(Ranks Hovis)*, a 1976 decision by the then Assistant Commissioner of Patents regarding the patentability of live organisms, in particular isolated strains of micro-organisms. The submission views the Deputy Commissioner's 1995 finding in *Kiren-Amgen Inc.v Board of*

1 1919 Act, s.38(a)(1).
2 S.155.
3 (1959) 102 CLR 252
4 1977 Act, s.2(1).
5 1977 Act, s.1(2)(a).
6 (1976) 46 AOJP 3915

Regents of the University of Washington[7] *(Kiren-Amgen)* as being inconsistent with *Ranks Hovis McDougall Limited* (see page 65).

Ranks Hovis found that a strain of a micro-organism with altered or improved "useful properties" resulting from a "man controlled biological process" represented patentable subject matter. Claims to new strains of *Fusarium per se* were not granted. However, claims defining the new strain of *Fusarium* isolated from soil, in the presence of culture medium of specified ingredients for the maintenance of the strain, were granted.

In *Kiren-Amgen*, the Deputy Commissioner considered whether a claim to an isolated and purified nucleic acid sequence was a discovery or patentable subject matter. He concluded that:

> *"Claims 14, 17, 18, and 55, which claim a 'purified and isolated' sequence limited to that specified in Tables V or VI, or limited to being 'essentially' the sequence encoding erythropoietin. These claims are directed to a molecule which is a fragment of the full chromosome. They do not claim the naturally occurring chromosome, or any other naturally occurring entity. By being directed to a purified and isolated DNA sequence they claim 'an artificially created state of affairs'*."

We consider both decisions to be consistent with the broad principle established by the High Court in *NRDC*. That is, a product or process that represents an "artificially created state of affairs" resulting from human activity and which has a practical utility or application, inherently represents patentable subject matter.

Information v Chemicals

The Senator's submission refers to gene and protein sequences as being mere 'sequence data' (page 33) or sequences 'which are informational not physical' (page 67). Gene patents usually define isolated nucleic acid molecules and isolated proteins by their chemical structure. The chemical structure is conveniently presented as a sequence of letters corresponding to the type and order of nucleotide bases in a nucleic acid's molecule, or the order of amino acids in the case of a protein molecule. These sequences are commonly referred to as 'gene sequences', 'protein sequences' or 'amino acid sequences', respectively.

Because of the way gene sequences are described, the words "code" or "information" are often associated with them. This often leads to the mistaken belief that gene sequences are mere information rather than something physical. Genes and proteins are in fact physical chemicals and not abstract concepts.

Consequently, it would be a significant departure from Australian patent law and long established practice to regard chemical entities, including isolated nucleic acids and proteins that are defined by their chemical structure or formula as mere information and unpatentable subject matter.

The *NRDC* judgement provides guidance as to the nature of the distinction between invention and discovery in the patent context. The decision recognizes that discoveries enter the realm of invention where ingenuity is applied to produce a useful result and an invention is patentable if it gives rise to an 'artificially created state of affairs' in the 'field of economic endeavour'. Isolated molecules are considered to be an artificial state of affairs and patentable subject matter if useful in a field of economic endeavour. Isolated molecules for which no

[7] [1995] APO 61; (1996) AIPC 91-231; 33 IPR 557 (19 October 1995)

useful function or intended use is disclosed are considered curiosities or discoveries and do not meet the patentable subject matter test.

Current Situation in the US

The Committee may be aware that on 29 March 2010 a decision was handed down in the action brought by the American Civil Liberties Union (ACLU) and eleven other plaintiffs against Myriad Genetics Inc (Myriad) and the United State Patents and Trade Mark Office (USPTO). The application challenged the validity of 15 claims contained in seven of Myriad's 23 patents relating to the BRCA 1 and 2 isolated gene sequences and their uses. Judge Sweet of the US District Court in the Southern District of New York ruled that "*isolated DNA containing sequences found in nature*" constitutes unpatentable subject matter under s101 of US Patent Law and extant US legal precedent.

Myriad has announced that it will appeal the decision to the Court of Appeals for the Federal Circuit (CAFC) and will continue to vigorously defend this litigation. This suggests that if necessary the litigation will be pursued to the US Supreme Court.

Judge Sweet dismissed plaintiff's claims for constitutional violation by the USPTO. As such the District Court ruling is not binding on the USPTO and there is no change in current USPTO policy.

Given Myriad's announcement that it will appeal this decision and in the absence of a change in current USPTO policy, the situation in the US is unlikely to change significantly until at least a supporting ruling by the CAFC on appeal.

Express Exclusions of Diagnostic Methods and Morality and Ethical Issues

IP Australia recognizes that an express exclusion of diagnostic, therapeutic and surgical methods for the treatment of humans and animals would not contravene the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The European Patent Convention has in fact adopted such a restriction.

We note, however, that the European approach to Article 53(c)[8] of the European Patent Convention 2000 extends only to these methods when practiced <u>on</u> the human body. That is, diagnostic methods performed on samples of tissue or fluids obtained from patients are patentable. While methods for the treatment by therapy are excluded, the EPO does grant patents for therapeutic and medicinal products for use in such therapeutic methods.

It is worth noting that the European challenge to the diagnostic methods embodied in the BRCA patents on the basis that the methods contravened Article 53(c) [then Article 53(4) EPC 1973] was unsuccessful. The Technical Board of Appeal held that the exclusion applies only if the diagnostic method is performed on a living human or animal body. The claimed BRCA methods are practiced on samples and therefore the methods were found to be patentable.

The Senator's submission questions whether the patenting of gene-based technology is ethically, socially or morally appropriate (page 37). The Australian courts have established the principle that it is for Parliament, not the courts or IP Australia to decide whether matters

[8] Article 53(c) states that "European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

of ethics or social policy are to have any impact on what types of inventions or subject matter are patentable.[9]

Article 53(a)[10] of the European Patent Convention is an example of a regulation which provides for the exclusion of European inventions which by way of publication or exploitation, would be contrary to "*ordre public*" or morality.

In practice the EPO interprets this morality exclusion narrowly.[11] For example, in Europe in 1992 the 'Relaxin' gene patent EP 112149 was granted to the Howard Florey Institute of Australia. This patent comprises claims to sequences *per se*[12] and was subject to opposition on many grounds, including that the patent contravened morality or *ordre public*. This view was dismissed by the Opposition Division in 1995 on the basis that the patent would not be viewed by the public as too abhorrent to be patentable.[13]

More recently, the EPO Technical Board of Appeal also reaffirmed their approach to gene patents in view of Article 53(a) by deciding that the claimed BRCA diagnostic methods did not offend morality or *ordre public*.[14]

Number of Gene Patents

Senator Heffernan's submission suggests that in the future there will be a significant number of patents that claim an isolated gene (see pages 43-45). We would like to draw the Committee's attention to paragraphs 7.10-7.12 of our joint submission where we discuss the number and changing subject matter of gene patents and to Appendix C of that submission where we present the classification of biotechnological and genetic based inventions.

The Senator's submission notes Dr. Moir's assessment of 42,326 gene patent applications and 14,306 granted patents (see page 44). We however draw the Committee's attention to the fact that Dr Moir's assessment is based on analysis of the number of patents falling within the whole C12N subclass. The C12N subclass covers biotechnology inventions such as isolated micro-organisms, culture media, and methods for introducing DNA into cells. This subclass includes biotechnology inventions which, although related to genetic engineering technology, are unlikely to include claims to isolated gene sequences *per se* or diagnostic methods based on the use of isolated gene sequences. A more accurate way of estimating the number of gene patents likely to claim an isolated sequence *per se* is by analysing the C12N 15/12 subgroup. Patents that claim methods of using an isolated gene sequence *per se* are likely to be accorded a class make of C12N 1/68.

IP Australia maintains that, since the publication of the human genome, the number of patents that claim a novel, isolated gene sequence *per se* that represents the commonly occurring form of the gene sequence will continue to decrease. We do not dispute the present research trend towards assessing the relationship of multiple genes to disease. However, given the publication of the human genome, patentable technology derived from this research will tend

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9 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065.

10 Article 53(a) states that "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States".

11 Journal of Intellectual Property Law & Practice, 2007, Vol.2, No. 2, page 61-62.

12 For example, claim 1 was for 'A DNA fragment encoding Human H2-preprorelaxin, said H2-having the amino acid sequence depicted set out in figure 2.'

13 *Bioethics and Patent Law: The Relaxin Case*, WIPO Magazine, April 2006. Available online at http://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html

14 See decisions T 1213/05 and T 0080/05.

to cover diagnostic methods, albeit the methods might rely on the analysis of multiple genes and/or identification of variations or mutations in a gene sequence.

The Senator's submission refers to two gene patent applications, first raised by Dr. Palombi at the public hearing[15], as an illustration of the ongoing trend of filing for protection of human genes. With respect to these applications we note the following.

Application WO 2009/083968 A1 (hereafter referred to as '3968) entitled 'Novel Protein' relates to a laboratory synthesised cDNA, reverse transcribed from mRNA which is expressed in some human tissues including kidney, pancreas, testis and white blood cells. The synthetic protein encoded by the cDNA was shown to have anti-viral, anti-cancer and pro-inflammatory properties. Therefore, the protein may find use in the treatment of cancer, infectious diseases and immune disorders.

Application WO 2009/091826 A2 (hereafter referred to as '1826) entitled 'Compositions and Methods Related to a Human CD19-Specific Chimeric Antigen Receptor(H-CAR)' relates to a genetically engineered molecule, known as a chimeric antigen receptor, for use in immunotherapy and the treatment of disorders such as no-Hodgkin lymphoma and leukaemia malignancies.

Firstly, it is important to note that both '3968 and '1826 are patent applications and not granted patents. Neither application has proceeded to examination in any jurisdiction. It is often the case that the claim set will change before a patent is granted because patentability issues are raised during examination.

Application '3968 does include claims to isolated human polypeptide and nucleic acid sequences. However, the published document includes a search report that identifies relevant art that may be prejudicial to the novelty and inventiveness of the sequence claims.

At the public hearing, '1826, was put forward by Dr. Palombi as indicative of a patent application covering an invention "derived from the human body and that has been isolated from it".[16] This may be based on a misunderstanding of the nature of the invention. 'Chimeric' proteins are engineered proteins formed by the fusion of a part of one protein with part of another protein. The engineered and chimeric molecule defined in the claim does not have a naturally occurring counterpart in the human body. The generation of such a chimeric protein without human invention is not possible. All the examples and embodiments disclosed in the application are engineered. The application does not seek to protect a molecule which has a corresponding equivalent in nature.

Claim Interpretation

The Senator's submission considers that IP Australia's practice of granting claims over isolated nucleic acid molecules *per se* without limiting the patent monopoly to the molecule's practical use contradicts IP Australia's position that it only grants patents to isolated molecules for which a practical use or application exists (see pages 65 and 66).

A patent specification includes the description of the invention and the patent claims. The description provides sufficient details of the invention to enable it to be understood and reproduced. For an invention to be patentable, the description must disclose a practical use for it.

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15 Hansard, Senate Community References Committee, CA4, 14 September 2009.

16 Hansard, Senate Community References Committee, CA4, 14 September 2009.

The claims define the invention and the scope of legal protection provided by the patent. There are three basic types of claims – product, method and use claims. Product claims define the components of a material entity such as a chemical compound or a device. Method claims can define a way of making a product and use claims define a way of using it. In all technologies, a patent specification may include all types of claims.

New chemical products *per se* are patentable subject matter in the same manner as new mechanical products are patentable. The language used in a claim defining a new and inventive chemical or apparatus *per se* (ie a product claim) does not need to reflect the intended use of the chemical or apparatus. As stated above, this information must be included in the description. Gene patents that disclose a useful isolated nucleic acid usually claim the isolated product *per se* and also protect methods of using the molecule in additional method and use claims. Such claims usually cover methods for diagnosing a disease or condition associated with the molecule.

It would be a significant departure from patenting norms if patents were not granted to chemical products or apparatus *per se* but only granted to methods of using the products.

Crown Use

Senator Heffernan's submission to the Committee states that no evidence was presented to the inquiry which demonstrated the exercise of the current Crown Use powers when appropriate (page 29).

As outlined in our joint submission to the Committee (see page 30), the Crown Use provisions permit certain government entities to use, and to authorise others to use, patented inventions without permission from the patent owner in certain circumstances. The government would have to pay the patent owner or exclusive licensee remuneration for that use. To IP Australia's knowledge, these provisions have rarely been litigated and interpreted by the courts.

The Crown Use provisions have recently been reviewed by the Australian Law Reform Committee (ALRC) and ACIP. The main recommendations of the ALRC were[17]:

- a policy be developed to set out the circumstances in which it may be appropriate for a government agency to exploit a patented invention under the Crown Use provisions for the purposes of promoting human health; and

- remuneration paid to the patent owner or exclusive licensee must be paid promptly and must be just and reasonable.

ACIP's main recommendations were[18]:

- The patents legislation be amended to ensure that, prior to any use of a patent, the Crown or authorised user should make genuine efforts to obtain authorisation from the rights holder, exploit the IP on reasonable commercial terms and seek to make an agreement on the terms of use within a reasonable period of time.

- Federal Minister / State Attorney General approval must be obtained prior to use of a patent being made.

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17 Report 99 *Genes and Ingenuity*, June 2004, recommendations 26-1, 26-2 and 26-3.

18 *Review of Crown Use Provisions for Patents and Designs*, November 2005, recommendations 1-3.

- State and federal government organisations should be made aware of the new legislative changes and their obligations.

The Minister for Innovation, Industry, Science and Research considered these issues and determined that legislative changes were not warranted at this stage because there is insufficient evidence of a significant problem. However, in order to ensure that government agencies took a correct and consistent approach to these provisions, in March 2009 the Minister wrote to relevant Commonwealth and State government Ministers detailing the obligations of governments when exercising Crown Use powers. IP Australia also produced an information sheet for the general public which is publicly available on our website. Together, these initiatives form a coherent national policy on Crown Use powers.

IP Australia understands that the Crown Use provisions are used by government agencies, however we do not have information on how often this is. Mr Chris Reid, General Counsel to the Department of Health and Ageing, told the Committee in the hearings of 20 August 2009[19] that there was some discussion between State governments about whether Crown Use was a way to ensure the public had reasonable access to the BRCA breast cancer test. However, such action was not warranted because Genetic Technologies Limited withdrew its demand that State laboratories discontinue testing. It therefore appears that the Crown Use provisions are only used occasionally because the circumstances that warrant it rarely occur, rather than the provisions being inadequate.

Compulsory Licensing

Senator Heffernan's submission to the Committee highlights that there have only been three applications for a compulsory licence and none have succeeded. It also claims that the current compulsory licensing provisions are a barrier to the working of inventions in Australia (see page 29).

As outlined in our joint submission to the Committee (see paragraph 9.2), the compulsory licensing provisions require a patent holder to grant a licence to another to work their patented invention in certain circumstances. Such a licence would only be granted upon application to a court and where the reasonable requirements of the public are not being met. Examples of where public needs are not being met include where a trade or industry is unfairly prejudiced or demand for the patented product is not reasonably met because of the applicant's failure to adequately supply the product on reasonable terms.

The compulsory licensing provisions were reviewed by the Intellectual Property and Competition Review Committee (IPCRC) in 2000.[20] The IPCRC recommended that the provision be changed to an explicit competition test. The Government accepted these recommendations in part, deciding to maintain the existing test and add a competition test as an additional ground on which a compulsory licence can be obtained. The ALRC also reviewed these provisions[21], agreeing that a competition-based test should be added and that the scope of the 'reasonable requirements of the public' test be clarified. As a consequence, the Government added a competition test to the provision in 2006.

To IP Australia's knowledge this provision has rarely been litigated. However, this does not necessarily mean that the provision is not effective. The IPCRC was informed that this provision has a continuing impact on licence negotiations, notably between foreign rights

19 Hansard, Senate Community Affairs Committee, CA27, 20 August 2009.

20 *Review of intellectual property legislation under the Competition Principles Agreement*, Final Report, September 2000, pp. 162-163.

21 Report 99 *Genes and Ingenuity*, June 2004, recommendation 27-1.

owners and potential users of the patents in Australia. Similarly, several submissions to the ALRC inquiry said that the threat of compulsory licences induces patent holders to enter into voluntary licences. The compulsory licence provision is potentially powerful and its usage may increase if users of patents have greater awareness and understanding of the options available to them.

Experimental Use

Senator Heffernan's submission to the Committee claims that an express research exemption may be useful but will not be a substitute for ensuring that patents are only granted for inventions of a very high standard (see page 29).

The introduction of an experimental use exemption was considered by the ALRC. The ALRC found that it would be helpful to remove the current uncertainty in the research sector on this issue and recommended that an exemption be introduced.[22] ACIP conducted an extensive review of the issue and in 2005 similarly recommended that an exemption be introduced.[23] ACIP considered the option of introducing a statutory licensing regime like that in existence for Copyright, however it found that such a system would be very complex to establish and be a partial solution at best.

IP Australia has further consulted on the issue[24] and, as outlined in its Supplementary Submission to the Committee (see page 5), is currently developing legislation to introduce a statutory research exemption as part of a package of reforms to the patent system. The general consensus is that such an exemption is the best way to provide patentees, researchers and businesses with greater certainty about the types of experimental activities that can be done without infringing a patent.

Databases

Senator Heffernan's submission to the Committee describes functions of a 'patent transparency register' and a potential role for IP Australia in its development and maintenance (see page 72).

IP Australia is obliged under the *Patents Act 1990* to publish patent specifications and bibliographic information. IP Australia's free online databases such as AusPat and APPS (AU Published Patent data Searching) enable users to identify the portfolios of patent owners, the ownership of patents in specific technologies and licensing and mortgage details.

Users can put together complete lists of patents owned by a particular person or organisation, or in a specific technology, and drill down to the details of each patent. IP Australia believes that it is more appropriate and efficient for users to identify those organisations and technology fields that are of interest to them, rather than for the Government to expend considerable resources attempting to tailor information to suit a wide range of interests.

IP Australia is also currently developing an e-Dossier system that will provide public access to all documents on patent application files. Such a facility is already provided by some IP offices including the EPO and the USPTO. This new facility will help to increase the transparency of patenting decisions to the public and, together with IP Australia's existing databases will serve as a powerful source of information on Australia's patents and patenting. The e-Dossier facility is expected to be operational in 2011.

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22 Report 99 *Genes and Ingenuity*, June 2004, Chapter 13, recommendation 27-1.

23 *Patents and Experimental Use*, ACIP, October 2005.

24 *Exemptions to Patent Infringement*, IP Australia, March 2009.

Governance of IP Australia.

The Senator's submission gives the impression that IP Australia is somehow not "performing its assigned task effectively and lawfully" and has "become vulnerable to inappropriate influence" (see page 70).

To assist the Committee to understand IP Australia's operations and responsibility, the following background information and comment is provided.

IP Australia is part of the Innovation, Industry, Science and Research portfolio. As such the portfolio has responsibility for all three elements comprising the innovation process, namely:

- creation of intellectual property which is supported through various R&D programs administered by the portfolio;
- protection of intellectual property through services provided by IP Australia; and
- exploitation of intellectual property through collaboration and/or commercialisation supported by a range of programs administered by the portfolio.

IP Australia is required to administer the patents system according to the Patents Act and Regulations and how these have been interpreted by the Courts, and in doing so considers an application for an intellectual property right with the interests of the applicant, the general public and other third parties.

In carrying out this role, IP Australia is accountable to the Government, the Parliament and to the Australian public. It is required to report on its operations and performance annually to the Parliament. IP Australia provides this report as part of the Innovation, Industry, Science and Research portfolio. Also as a government agency, IP Australia is required to uphold the Australian Public Service Values particularly in being required to provide services fairly, effectively and impartially.

IP Australia's operations are also oversighted by ACIP. ACIP is an independent body which advises the Minister for Innovation, Industry Science and Research. It comprises members from industry, the legal and attorney professions, and academia. As part of its functions, ACIP has an ongoing role in monitoring the performance of IP Australia and in providing advice that will assist in improving IP Australia's performance outcomes.

IP Australia recovers more than 95% of its costs by charging fees for its IP rights services. IP Australia is not unique in this respect within the Australian Public Service. The Therapeutic Goods Administration, the Australian Quarantine and Inspection Service, the Australian Pesticides and Veterinary Medicines Authority are examples of similarly cost recovered regulatory agencies, which are funded by the particular groups or sectors being regulated. IP Australia, like all these other regulatory agencies, is required to comply with the Australian Government Cost Recovery Guidelines which were adopted in December 2002. In complying with these guidelines, IP Australia has to ensure that its fees and charges are consistent with the Government's policy objectives. Cost recovery agencies are required to develop a Cost Recovery Impact Statement which has to be reviewed every five years.

It is suggested in the submission that it is in IP Australia's interest to encourage more patent applications as this will create more revenue. In response to that it should be noted that IP Australia's public education and awareness strategy is not directed to encouraging more applications. The strategy is directed to informing businesses and individuals about intellectual property and how it can be protected, so that they can make informed decisions about whether to seek protection or not. Furthermore, the patent reforms currently being

progressed through the IP Reform Project, will in some way reduce the number of patent applications being filed due to the higher standards for patentability being proposed.

Other Mechanisms for Addressing Perceived Public Health Issues

As discussed in IP Australia's Supplementary Submission (pages 3 to 6), the Committee may wish to consider other mechanisms for addressing public health issues. The UK's Licence of Right scheme encourages the uptake of licences and the sharing of patented technology. Patent owners receive reductions in annual renewal fees in exchange for granting a licence to anyone who wants one. Similarly, patent pools are a means of reducing the transaction costs for users who need to identify relevant patents and seek cross licensing arrangements with multiple individual patent holders. Non-patent mechanisms such as the Pharmaceutical Benefits Scheme can also be used to ensure affordable access to cost-effective health care.

I trust that the information provided in this letter is of use to the Committee. Should you require elaboration on any of the above issues, we would be happy to assist. We look forward to the release of your report.

Yours sincerely

Fatima Beattie
Deputy Director General