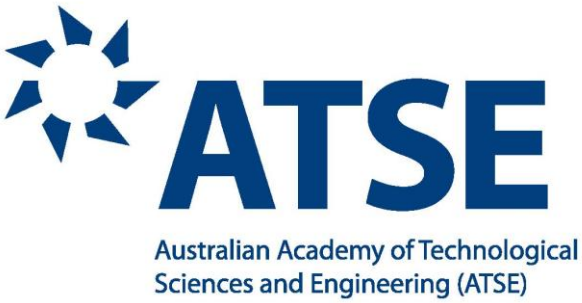

Senate Inquiry into the

Patent Amendment (Human Genes and Biological Materials) Bill 2010

A submission by the

Australian Academy of Technological Sciences and Engineering (ATSE)

February 2011

Australian Academy of Technological Sciences and Engineering

Submission to the Senate Inquiry on the Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Academy of Technological Sciences and Engineering (ATSE) welcomes this opportunity to contribute its views on the important issue of gene patents. There appears to be considerable misconception of the issue and ATSE would like to provide background and understanding to assist with the debate on this issue.

Executive Summary

Revision of Australia's patent laws is timely and ATSE understands the concerns of the Senators expressed in the proposed Private Members' Bill.
However, ATSE believes that:

- The proposed Private Members Bill would not rectify these concerns and, indeed, would be likely to have the opposite effect.
- The Bill in its current form would have unintended consequences arising from some of the proposed wording, in particular, terminology such as "*substantially identical*" and "*however made*".

Consequently, ATSE contends that there are likely to be several serious negative consequences if this Bill is approved. These include

- Contravention of international agreements
- Inhibition of scientific research
- Loss of Australian competitive advantage
- Loss of investment
- Reduction in the quality of medical products and medical care available to the Australian community
- Longer patent examination times and increased litigation

It is therefore recommended that the Senate consider the following:

1. **Reject the Private Members' bill** and replace it with modifications to existing patent legislation that :
    - Establish the research use exemption for non-commercial research
    - Tighten up terminology so that Australian patent laws and examination practices are consistent with and as rigorous as those of our trading partners
    - Does not define additional categories for exclusion since this would lead to legal arguments over terminology, delays and increased patenting costs
2. **Initiate measures at IP Australia** to ensure rigorous patent examination practices that limit claims to those which are truly inventive, novel and useful.

ATSE

The Australian Academy of Technological Sciences and Engineering is an independent body of 800 eminent Australian applied scientists and engineers, including molecular biologists and geneticists, from industry and academia. The Academy provides a forum to study and discuss issues relevant to the formulation of public policy for technological sciences and engineering based activities, and the communication of expert advice to government and the community. It engages in international scientific relations and fosters science and technology education and public awareness of applied science technology and engineering.

Background to the Submission

On 24th November 2010, Senators Coonan, Heffernan, Siewert and Xenophon tabled a private member's bill with the title "A Bill for an Act to amend the *Patents Act 1990"* to prevent the patenting of human genes and biological materials existing in nature, and for related purposes. It asks that section 18 (2) of the current patent act "Human beings, and the biological processes for their generation, are not patentable inventions" be replaced with

"18 (2). The following are not patentable inventions:
(a) human beings, and the biological processes for their generation; and
(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature."

"***Biological materials"*** are later defined in section 18, as "includes DNA, RNA, proteins, cells and fluids."

The bill has been referred to the Senate Legal and Constitutional Affairs Legislation Committee for inquiry and reporting in June 2011.

On 26 November 2010, the Senate Community Affairs Committee tabled its Report on the Inquiry into Gene Patents. The Inquiry, commenced in 2008, was meant to investigate whether patents should protect genes. This Report fell short of determining the issue and the Committee deferred determination, citing ongoing legal developments in both the US and Australia, including the recently introduced private members' bill, *The Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

The Committee did recommend numerous reforms in the areas of patent law involved in respect to gene patenting, including:

- higher thresholds for novelty and invention
- higher standards for description of patent claims
- broad research exemption, and
- amendments to provisions on compulsory licences and crown use.

The Committee recommended that the Government provide a response to the Inquiry, the Australian Law Reform Commission (ALRC) report of 2004 and the patent reviews by IP Australia and the Australian Council on Intellectual Property, in mid-2011.

The issue of gene patents will continue to be reviewed over the next year, including as part of Australian litigation involving patents on two breast cancer genes.

What are the issues this Bill was designed to address?

Excerpt from the Explanatory memorandum:
"The purpose of this Bill is to ***advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.***
These biological materials even if they have been isolated, purified or synthetically made have not been transformed from products of nature into products of humankind.

Thus the Bill (a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), (b) reinforces the applicability of the distinction between discovery and invention and (c) applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made."

Thus, there are a number of concerns:

1. Concerns that natural materials ***as found in nature*** should be freely available to all, for research and application purposes
2. Concerns that the existence of a patent covering a biological material might inhibit the course of research and thereby deprive society of new knowledge and future medical advances
3. Concerns that the availability of important medical treatments or diagnostic tools might be too expensive and/or not widely available, thereby depriving individuals of the best medical care
4. A perception that increased competition will provide wider and less expensive access to new diagnostics and drugs

Another concern voiced in discussions was:

5. Concerns that the genes of individuals might be patented and therefore "owned" by someone other than the individual

Does the proposed Bill address the above issues or can the same aims be achieved in other ways?

Point 1: Concerns that natural materials, as found in nature, should be freely available to all, for research and application purposes

Point 5: Concerns that the genes of individuals might be patented and therefore "owned" by someone other than the individual

These points are already addressed without new legislation. Materials in their natural state, whether from an individual or more generally, do not meet the criteria for

patentability because they no longer meet the patent criterion of inventiveness, as discussed under Point 3 below.

ATSE believes that rigorous application of existing patent criteria during the examination process, consistent with international standards, would effectively address these two concerns without need for the proposed Bill.

Points 1 and 2: Concerns that patents covering natural materials might inhibit the course of research

Senator Heffernan's speech suggests that current laws stifle research. However, there are few if any examples that suggest this is the case. Most medical research institutes are not inhibited by patents and, indeed, all are focussed on patenting their own research in order to bring in much needed research funding to ensure that research continues in this country. A commercial manager from one of Australia's largest medical research institutes argues that he was unaware of any patent rights which had hindered basic research at his institute. As an example, it was pointed out that there are over 5,500 global scientific publications relating to the controversial BRCA1 gene, which is associated with breast and ovarian cancer. This statistic does not support Senator Heffernan's assertions that patents covering these genes means that basic research is being hindered.

The patent system is the preferred way of informing the research community about inventions because patents must be published during the course of patent prosecution. On the other hand, trade secrets can be kept away from the research community forever.

It is recognised that new medicines and diagnostic products are expensive during the time they are covered by a patent. Like all such products whether they are biological or chemical in nature, the high cost of research and development and particularly satisfying the regulatory system requires significant investment. It is a high cost, high risk endeavour. In the absence of patent protection no commercial entity would invest the huge sums required. The benefit of the patent system in providing a period of exclusive market access for the inventor is that many life saving medicines and diagnostics are now available. Patents have a finite life and, as is now demonstrated with generic medicines, the costs have significantly declined once the patent has expired. There would be no generic medicines if the original product had not been covered by a patent.

Successive Australian governments have demanded that universities and research institutions commercialise any research that is applicable to products or services. Many of the granting bodies provide grants to do this and others expect an analysis of the usefulness of the developed technology to commercial applications to be included in the applications. The ability to patent, and thus commercialise, technology developed by our institutions is one of the criteria for providing funding in many grants programs. It provides a return on investment for the money provided by governments for research and development. It keeps technology development in Australia longer, provides jobs and increases the likelihood of significant financial returns to the research institutions.

It has long been recognised that current Australian practice regarding research exemptions from patent coverage need clarification, and these research exemptions would be a better focus for the political debate, than the additional wording proposed by

the Bill. Establishment of the research exemption would allow free and untrammelled use of all biological materials for the purposes of non- commercial research. The research exemption should cover all patents and not just those in the medical and biological fields. This would meet two needs:

- Allowing scientific research to advance unhindered
- Allowing improvement to current products and development of new ones, thereby providing better financial returns to the researchers, the original inventors and the Australian biotechnology industry.

ATSE recommends that introduction of a research use exemption into Australian patent law, as recommended by previous reports, is the most effective way of achieving the purpose of the proposed legislation.

Point 3: Concerns that the availability of important treatments or diagnostic tools might be too expensive to be widely available, thereby depriving individuals of the best medical care

Genes and other biological materials *in their natural state or setting* would not be patentable under current law, based on the need for an inventive step and demonstration of utility, for a claim to be granted. Additionally, since the publication of the human genome sequence, grant of such a claim is even less likely since a plethora of human and other gene sequences is published and freely available.

What may have been viewed as patentable 10 years ago, when isolated single human genes were difficult to identify, is now no longer considered as inventive; to isolate a human gene is now an obvious thing to do, with technology widely available to all.

It is only when research has been done to understand why a certain gene or material is important and what relevance it has to a particular disease, that it may be patentable, if novelty, non-obviousness and utility can be proven to the satisfaction of the patent examiner. Thus, a proposal to deny patentability of biological materials has been superseded by scientific progress, as far as natural (untransformed) materials are concerned.

ATSE believes that the state of the science and the consequent potential to patent has moved past the fundamental concerns on patenting of gene sequences as they are found in nature, that the proposed legislation purports to address.

That blocking patentability of *otherwise patentable (i.e. transformed) biological materials* could open up the opportunity for a larger number of players to develop a treatment or a diagnostic test, with competition resulting in a lower price, is a premise that is seriously flawed. It is highly unlikely that this would be the outcome of such a change.

The key is consideration of the nature of the inventive step that makes a particular product or process patentable. This inventive step might involve one or more of

- Discovery of the *function* of a biological material allowing prediction of novel utility if it were to be transformed into a treatment or test, and demonstration of that utility
- Presentation of the biological material *in modified form (transformed*) to enhance its activity, specificity or safety
- *Production of the biological material in a novel way,* making it available for development in an active form or at lower cost.

Patent documents must define the material being utilised (including closely related materials expected to behave in a similar fashion) but will also require claims to the use of the material, for example for diagnosis or therapy, the method of testing or the design of a drug that would inhibit or enhance the activity of the particular material, thereby identifying the inventive steps that have transformed a natural material into a particular useful product.

If the ability to define a particular material, transformed into usable form, as part of patent claims were blocked, then a normally patentable invention such as a novel use, production or format of such a material would become meaningless. Or if a patent could be constructed in such a way as to make an invention patentable separate from the material which is its subject, then the way would be open to others to develop alternative approaches to achieve the same ends using the same materials, denying the original inventor of the transformed material any rights to protection of their invention.

The most likely outcome of this situation is that inventions would not be developed where effective patent protection is not available, and so if the proposed legislation were implemented, Australians could be denied access to important new tests or treatments, the opposite effect from that sought by the Bill's proponents.

ATSE believes that implementation of the proposed legislation would not increase but rather decrease the availability of treatments and tests for Australians; the opposite of the ends sought.

Point 4: increased competition will lead to less expensive diagnostics and treatments

It takes many years of development beyond the initial period of research to develop a new diagnostic test or drug. Diagnostics are less expensive to develop and require less intensive clinical testing, as there is no issue of safety as there is for a medicine that is injected or taken orally. However, it still takes several years and expensive clinical trials before regulatory approval to sell the product is given. The resulting product has set standards of effectiveness, reproducibility, specificity and expiry. No commercial concern with the capability to undertake the expense of this process would take this on without the promise of a competition-free period in which to recoup the costs and make some profits. Conversely, any attempt to short cut the development process and generate a cheaper product is likely to undermine the regulatory system which is there to protect the community from inferior or unreliable products.

ATSE believes that the lack of ability to patent would not lead to increased competition and the likely outcome would therefore be either that new tests or treatments would not be developed, or inferior products being developed with serious impacts on the reliability and safety of health care.

The recently released Human Papilloma Virus vaccine, for prevention of cervical cancer in women, was based on Australian research and initially licensed to an Australian company before being on-licensed to Merck. From the point of its first development, it took 15 years and hundreds of millions of dollars to get the vaccine to market. This development would not have happened without patents to ensure the pharmaceutical company licensee a period of market exclusivity, providing it with a reasonable expectation of a commercial return on its investment.

Potential adverse consequences of the proposed Bill

1. International Agreements could be contravened

- Australia is party to international agreements on patents and trade - since the proposed amendments are contrary to these agreements, it is more appropriate to come to a consensus with our trading partners on this issue and then, once agreement is reached, amend the Australian Patents Act 1990 to be consistent with our international obligations. The willingness for international companies to introduce products in Australia would be severely and negatively impacted and patent laws inconsistent with those of our trading partners could be seen as trade barriers.

2. Local product development and medical care for Australians may be compromised

- It is important that Australia's patent regime be well aligned with those of other key markets, particularly the USA, Europe and Japan. If this does not occur, then the ability to develop important new products for sale in the Australian market will be compromised, even if these products are widely available elsewhere.
    - A too strict regime (for example including the new proposed amendments) is likely to discourage companies (local and overseas) from seeking or prevent them from obtaining patent protection for new products in Australia. This means that effective products available elsewhere may not be developed for, or sold in, the Australian market, thus provoking one of the very outcomes that the Senators were keen to prevent.
    - On the other hand, a too-generous regime here (examination process not sufficiently rigorous) as exists at present, can result in patents being granted in Australia with overly wide claims that are not granted in other countries. This can prevent the subsequent patenting (and marketing) in Australia of novel but related products, even where these products represent a significant improvement over the first generation product.

This emphasises the need for modifications to patent examination processes as recommended by the 2010 Senate Community Affairs Committee Report, rather than the proposals in the Private Members' Bill under discussion.

- Outside of the medical area (e.g. in agriculture) there will be some inventions that have more of a national focus. Local patent protection will be a key element in encouraging and funding the development of such inventions to meet national needs.

3. Inhibition of future scientific advances

- Application for a patent establishes the inventor's priority of invention and allows associated scientific data to be published both via publication of the patent and in the scientific literature. This information then becomes widely available and can form the basis for further research and invention and development of the next generation of products. This is particularly true where the local patenting regime includes an exemption from infringement of a patent where the work done is for research purposes only.
    - The inclusion of such a provision will allow the "free and unfettered access" to genes and their products sought by the proposed new Bill, provided that this access is directed to academic research, while allowing the original inventors to pursue commercial application of their original invention.
- If ability to patent effectively a new invention is restricted as in the proposed legislation, only secrecy can protect this new invention. As a result, publication of much important scientific data is unlikely to occur and future research and scientific advances inhibited.

4. Loss of competitive advantage for Australian inventors

- The ability to protect intellectual property (IP) by effective patenting is a key aspect of industry development. It sets out, in a tangible way, what a company or research group can claim as its own for the purpose of attracting investors or purchasers. Such investment is required to allow the research to be developed into a high quality product or service.
- If suitable patent protection for inventions is not available in Australia, then it is more likely that Australian inventions will be developed and commercialised elsewhere in the world, using non-Australian capital, with concomitantly lower benefits flowing back to Australia in the longer term.
- It is not just companies that apply for patent protection. A significant part of the research carried out in our medical and research institutes is protected by patents, allowing for inventions to be commercialised via licensing or formation of a start-up company. Commercialisation of research leads to jobs and revenue, which can be applied to future research. If the University of Queensland had not patented Ian Frazer's work on human papilloma viruses, both the university and the Australian company, CSL would have been deprived of the significant returns from the resulting vaccine for reduction of cervical cancer being sold by Merck.
- Wide patent protection is a key element in negotiation of the size and terms of royalties that local companies or research groups would obtain if they license their inventions to larger overseas companies. No patent in a country, means no

or smaller royalties, since a product could be sold in that country where there is no patent protection (but not elsewhere) without redress by the inventor.

5. Loss of Potential Investors

- Investors provide risk capital, to develop new drugs and diagnostic tests. In Australia, this is usually sourced from superannuation funds. The Investors undertake lengthy and detailed due diligence to understand the risks of such an investment. One of the main criteria for investment is that there are strong barriers to competition. This means patents with enough lead time to develop and then make some returns on the product before generic competition enters the market. No venture capital would be available to companies without patent protection and it is likely that most unpatented or weakly patented inventions would not be developed at all.

6. Reduction in quality of medical products

If the proposed legislation were passed, more groups might be encouraged to develop medical treatments or diagnostics, but they could not afford to provide the standard of products Australians require for a quality health care system. Meeting these high standards requires significant expertise and private investment that will only occur if products can provide reasonable commercial returns.

- Most molecular research labs could work up a test for the presence in a patient of a particular gene mutation such as the BRCA mutation, which predisposes to breast cancer. However the quality and reliability of a test developed in different research laboratories is likely to be highly variable, which could result in poor quality information being provided to patients and clinicians when the test is used. This is why most countries, including Australia, have strict regulatory regimes that control the type and quality of information validating a new product before it can be released to the market.
- Testing to meet regulatory requirements is a long and expensive process, particularly for drugs but increasingly for diagnostics as well. Testing over several years for effectiveness and reliability would require use of samples from or direct testing in hundreds or thousands of patients, as well as tight quality control to ensure purity and consistent performance of the drug or diagnostic. If investment funding is not committed to this process then fully registered drugs or diagnostics will not be available.
- A “research” version of a diagnostic may become available through government investment, but if it has not been properly validated, its reliability and comparability with other such tests will be in doubt. The impact of a false positive test (e.g. for cancer) could be unnecessary surgery and/or chemotherapy, a significant cost for the health care system as well as considerable unnecessary anguish for the patient. A false negative would lead to patients remaining untreated for a condition that could result in death. A low quality, unreliable test is more damaging for a patient than no test at all.

"Substantially identical"

Very small changes in chemistry or sequence can be novel, inventive and have a large physiological effect. For instance, human granulocyte colony-stimulating factor (G-CSF) was discovered but not patented, in Australia. Neupogen was developed by Amgen Inc. as a treatment for neutropaenia in cancer. It is a 175 amino acid protein produced by bacteria into which the human G-CSF gene has been inserted. The drug has an amino acid sequence identical to the natural sequence, except for the addition of an additional methionine at one end, which is necessary for expression in the bacteria. Because the drug is produced in bacteria, it lacks the sugars that natural human G-CSF would have. This small change allows the manufacture of the drug and is the basis of the US company's patents. The Australian Institute did not benefit significantly commercially from its discovery.

"However made"

Insulin is a naturally occurring peptide hormone. It is used to treat diabetics, who can no longer make their own insulin. However, peptide hormones have different sequences of amino acid building blocks, depending on the species and, for many years, humans were treated with insulin isolated from a pig. This often caused immune reactions, leading to a lack of effectiveness and increased healthcare costs. This was rectified when the human sequence could be made by a recombinant method, in cell culture. It is highly unlikely that a pharmaceutical company would have spent the hundreds of millions of dollars on the research, development and all the clinical testing and subsequent trials without patent protection and a period of monopoly after regulatory approval.

7. The terminology of the Bill will cause unintended negative consequences:

The legislative amendment proposed in the private member's bill, if progressed in its current form, would exclude DNA, RNA, proteins, cells and fluids, which are identical or ***substantially identical*** to such materials as they exist in nature, ***however made,*** from patent protection.

For a start, this list ignores a whole range of other biological materials (lipids, carbohydrates, vitamins etc) which might equally be applied to the development of useful treatments or tests. The selection of these specific materials is due to an incomplete understanding of the nature of modern medical research.

The most significant consequence of the proposed wording "substantially identical" is that the courts would need to define the term (How much change would constitute 'substantially identical' – would this identity be defined in terms of chemical constitution, structure, function, safety or bioavailability ?) with inevitable uncertainties making patents harder to examine and to prosecute, resulting in higher patent costs and fewer new inventions getting to market with the outcome the opposite of the Senators' intentions.

The concept of "however made" ignores the possibility that a novel method of production may be the inventive step that makes an otherwise useless biological material available as a useful treatment or test and could deprive patients of important medical treatments, such as human insulin.

What changes, if any, are needed to Australian patent laws?

Proposed changes outlined in various reports including the 2004 Law Reform Commission Report, the Advisory Council on Intellectual Property (ACIP) Report, *Patents and Experimental Use*, October 2005 and its subsequent discussion paper and the report of the Senate Community Affairs Committee, November 2010, would have the effect of making the Australian patent system more consistent with those of our important trading partners and so are strongly supported by ATSE, provided that the changes are made in such a way as to provide much greater clarity to all parties than currently exists. Recommended measures include

- Research use exemption
- Higher thresholds for utility, novelty and invention, including requiring evidence of significant usefulness, revising descriptions of how "prior art" is defined and more closely defining "obviousness"
- Requirement for full description of the invention such that similar work could be carried out by others to obtain the same outcome

As discussed above, implementation of these changes would go a long way to meeting the concerns of the proponents of the proposed new legislation without provoking the negative consequences discussed above.

Recommendations

Based on the issues raised in this submission, ATSE would recommend to the Senate inquiry that it:

1. Reject the Private Members' bill

2. Replace it with a bill that :

    - Establishes the research use exemption for non-commercial research
    - Tightens up terminology so that Australian patent laws and examination practices are consistent with and as rigorous as those of our trading partners
    - Does not define additional categories for exclusion - this will lead to legal arguments over terminology, delays and increased patenting costs

3. Initiate measures at IP Australia to ensure rigorous patent examination practices that limit claims to those which are truly inventive, novel and useful.