AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

25 February 2011

Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Ms Dennett

Re: Senate Legal and Constitutional Committee Inquiry into the Patent Amendment (Human Genes & Biological Materials) Bill 2010

Thank you for the opportunity to contribute to the Senate's Inquiry into the Patent Amendment (Human Genes & Biological Materials) Bill 2010 (**the Bill**).

AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, encompassing medicines, medical devices and diagnostics, agricultural, environmental and industrial sectors in biotechnology.

AusBiotech shares the genuine concerns raised by the community and others:

1) that clinicians and scientific researchers should be free to conduct research on, or use, biological materials that may be the subject of patents;
2) that public access to beneficial tests and therapeutics should be improved; and
3) that the thresholds for patentability should be properly set and rigorously applied.

Although these concerns are broadly aligned with the purpose claimed by sponsors of the Bill, AusBiotech challenges how public interest in these three critical objectives can possibly be served by such a poorly constructed, albeit well-intentioned, Bill.

AusBiotech believes that the Bill fails completely to address community concerns about access to innovative medicines and diagnostics tests and that it actually places at risk such potentially life-altering products being available in a timely manner to the community in Australia.

AusBiotech strongly urges the Committee to recommend that the Bill be rejected.

AusBiotech suggests that the interests, concerns and needs of the wider Australian community, including patients, clinicians, researchers and the biotechnology industry, will be better served by Parliament focussing its energy on investigating amendments to the Australian Patents Act across all technologies, encompassing those involving genes and other biological materials and, importantly, those future technologies yet to be developed.

AusBiotech believes that the Australian Patents Act ought to deliver:

- patentability thresholds that are properly set and rigorously applied;
- a research use exemption enshrined in the law; and
- safeguards that are readily-accessible and adequate in their reach to ensure all Australians have access to beneficial technologies; this will protect the Australian community against a

patent owner who, in the course of exercising their patent rights, may act unethically or unreasonably in granting a license to a medicine, test or technology.

Further, AusBiotech urges the Committee to recommend the establishment of an additional safeguard in the form of a tribunal-like model and/or the appointment of a 'Patents Ombudsman' to whom the public, clinicians, researchers and industry could turn in the first instance with a grievance.

In this submission, AusBiotech explains what the unintended consequences will be of excluding biological materials from patentable subject matter on the access of Australians to life-changing medicines and diagnostics, on the ability of clinicians and researchers to conduct medical and agricultural research in this country and on the future of the Australian biotechnology and medicines industry.

AusBiotech would welcome the opportunity to appear before the Senate Committee to discuss this very important matter.

If you have any questions about statements in this submission, please do not hesitate to contact at or on

Yours sincerely

Dr Anna Lavelle
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Patent Amendment (Human Genes & Biological Materials) Bill 2010

Submission to the Senate Legal and Constitutional Committee Inquiry

February 2011

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Executive Summary

AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, encompassing medicines, medical devices and diagnostics, agricultural, environmental and industrial sectors in biotechnology.

AusBiotech shares the genuine concerns raised by the community and others that:

1) clinicians and scientific researchers should be free to conduct research on, or use, biological materials that may be the subject of patents;
2) public access to beneficial tests and therapeutics should be improved; and
3) the thresholds for patentability should be properly set and rigorously applied.

Although these concerns are broadly aligned with the purpose claimed by sponsors of the Bill, AusBiotech challenges how public interest in these three critical objectives can possibly be served by such a poorly constructed, albeit well-intentioned, Bill.

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AusBiotech strongly urges the Committee to recommend that the Bill be rejected and suggests that the interests, concerns and needs of the wider Australian community, including patients, clinicians, researchers and the biotechnology industry, will be better served by Parliament focussing its energy on investigating amendments to the Australian Patents Act across all technologies, encompassing those involving genes and other biological materials and, importantly, those future technologies yet to be developed.

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- patentability thresholds that are properly set and rigorously applied;
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- safeguards that are readily-accessible and adequate in their reach to ensure all Australians have access to beneficial technologies; this will protect the Australian community against a patent owner who, in the course of exercising their patent rights, may act unethically or unreasonably in granting a license to a medicine, test or technology.

Further, AusBiotech urges the Committee to recommend the establishment of an additional safeguard in the form of a tribunal-like model and/or the appointment of a 'Patents Ombudsman' to whom the public, clinicians, researchers and industry could turn in the first instance with a grievance.

In this submission, AusBiotech explains what the unintended consequences will be of excluding biological materials from patentable subject matter on the access of Australians to life-changing medicines and diagnostics, on the ability of clinicians and researchers to conduct medical and agricultural research in this country and on the future of the Australian biotechnology and medicines industry.

Background

The complexities of intellectual property rights over genetic materials and related technologies have been debated in Australia and elsewhere for over 10 years.

AusBiotech believes that much of the current discussion has occurred based on incorrect information. For example, the granting of a patent could never give the patent owner any rights over molecules in the human body and so the public's belief that a third party might "own their genes" is entirely incorrect. Similarly, the claim that access of Australian patients to the potentially life-changing BRCA diagnostic test will be improved if gene patents are banned is also completely false as the patent on the diagnostic test itself would still be allowable under the Bill.

As part of its contribution to the discussion around the patenting of biological materials, AusBiotech has developed several plain-English background briefing documents, which have been circulated widely including to parliamentarians, consumer health groups, members of the public and AusBiotech members. Two of these documents are at Appendix 1 and Appendix 2 of this submission.

Turning to the facts, Australians can today be assured that the mere identification of a naturally-occurring biological material such as a gene or protein is understood to be a discovery not an invention and thus is insufficient to secure a patent. The existing law in Australia and in other developed countries protects this difference by requiring patent applicants to additionally provide substantive evidence in support of the novelty, utility and inventiveness of the isolated or artificially generated biological material included in their technology.

Furthermore, with the tightening of examination practices in Australia and elsewhere in the world and with the success of the Human Genome Project which has resulted in the freely-available publication of the vast majority of human gene sequences, the incidence of granting weak patents, which may have contributed to certain concerns in the current debate, has greatly diminished. Therefore, the Bill is out of date and unnecessary.

AusBiotech is in favour of the continuous improvement and rigorous and consistent application of the Australian patent system, in relation to all technologies, to ensure the granting of high-quality patents and the continued distinction between discovery and invention. Further, AusBiotech welcomes the current reforms being proposed by IP Australia to "raise the bar" in relation to the thresholds of patentability.

Senate Inquiry into Gene Patents

In 2008, the community witnessed an attempt by the Australian licensee of the [patented] BRCA technology to insist that all future BRCA diagnostic testing be conducted "in-house" as was their right to exercise under the terms of the license from the patent owner. Understandably, this action caused high levels of concern among some sectors of the community, even though there was never any risk to a clinician's freedom to make a diagnosis or about whether some patients would or would not have access to the test. Rather, the issue revolved solely around how patent rights are exercised and, in particular, about a genetic test being conducted by a single laboratory, a fact in itself not remarkable since more than half of the 400+ genetic tests available to Australians today are performed in single laboratories. Unfortunately, some commentators did not fully understand this complex issue and possibly even believed that Australian women's access to the potentially life-changing BRCA diagnostic test would be improved if gene patents were banned.

The misguided premise that the very existence of gene patents posed risks to public health, stifled research and drove up health costs has been an important trigger for the establishment of the Senate Inquiry into Gene Patents.

In its submission to the Inquiry (Sub No. 75, 19 November 2009), AusBiotech expressed concern about the proposal of some to the Inquiry to exclude a wide range of genetic and related materials from Australia's patent law in order to remedy the community's genuine concern about equitable access to medicines and tests. AusBiotech argued that the relevance patents have to the biotechnology sector is shared globally, and that the need for patent protection is an essential starting point for development of potential life-enhancing products for communities. Further, AusBiotech predicted that future gene-based biomedical innovation would be jeopardised by a decline in investment in the biotechnology sector if it were to lack the certainty hitherto derived from patents.

Having received extensive evidence via 78 public submissions and eight public hearings, the Senate Committee reported on 26 November 2010 that the evidence did not show that gene patents were adversely affecting the provision of health care or the conduct of medical research in Australia. In the context of the current inquiry, it is important to note that the Senate Committee recommended that, at that time, there be no amendments to the Patents Act to expressly prohibit the patenting of genes. AusBiotech welcomed this finding and generally supported all of the Senate Committee's recommendations, which were intended to "ensure that patents do not adversely impact on healthcare and medical research" and "improve information and data collection on the uses and impacts of gene patents."

Notably the very recent Advisory Council on Intellectual Property (ACIP) 2010 report on Patentable Subject Matter, released on 18 February 2011, mirrored every other official report to government made on the topic of gene patents since 2004 in concluding that application of the test for patentability should be strengthened rather than the exclusion of genes and other biological materials from patentable subject matter.

Patent Amendment (Human Genes & Biological Materials) Bill 2010

The Bill fails to address community concerns

Ironically, the Government was given no chance to consider or respond to the Senate Committee's recommendations because on 24 November 2010, two days before the Senate report was tabled, the private members' Patent Amendment (Human Genes & Biological Materials) Bill 2010 was introduced in the Senate. The Bill was immediately referred to the Senate Legal and Constitutional Committee for inquiry and report.

While arguably well-intentioned, AusBiotech believes that the Bill's architects have ignored the fundamental basis for the legitimate concerns of their constituents over access to diagnostic tests; that is, it is the manner in which patent rights are exercised that may generate undesirable outcomes, not the existence of the patent itself. With this in mind, the focus of the Bill is undeniably misplaced.

AusBiotech notes that a 'mirror' Bill was introduced into the House of Representatives on 21 February 2011. Further, AusBiotech notes the remarks made by the Hon Member for Dickson in his first reading speech in the Lower House that foreshadowed that the Bill will have to be amended as a result of the scrutiny it will get in the Senate Legal and Constitutional Committee Inquiry. AusBiotech believes that this comment suggests that the Bill supporters now acknowledge its many deficiencies and are seeking to modify the drafting in response to the feedback from stakeholders that the Bill should be rejected since it fails to address community concerns and, worse, that it actually threatens patient access to new tests and therapeutics and risks damaging Australia's medical and biotechnology industries.

The scope and language of the Bill is unacceptable

Despite repeated claims by Senator Heffernan, the Bill is not narrow.

The Bill seeks to amend S18(2) of the Patents Act to exclude from patentability all 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 and add a proposed new subsection S 18(5) that defines a limited few examples of "biological materials." AusBiotech conversely finds the scope of the Bill broad and seemingly without limits and believes that it will encompass at least the following:

> genes, DNA, RNA, cDNAs, oligonucleotide primers, proteins, peptides and amino acids, lipids, carbohydrates, vaccines, bacteria, viruses, antibiotics, enzymes, hormones, immunoglobulins and other blood products, stem cells, anti-toxins, anti-venoms, skin and other tissues, allergenics, probiotics, antibodies, epitopes, monoclonal Abs, recombinant therapeutics and other personalised medicines.

Further, the Bill does not limit the source of the biological material, which could be from humans, animals (aquatic or terrestrial), insects, microorganisms, and plants.

AusBiotech foreshadows a profound negative impact of the Bill across diverse sectors of the Australian economy and community including those focused on:

- agriculture;
- animal production;
- diagnostics;
- vaccines; and
- biopharmaceuticals to treat major diseases such as arthritis, cancer and multiple sclerosis.

Far from advancing medical research, the feedback AusBiotech has received from researchers and industry about the vague and ambiguous language of the Bill (ie: "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") suggests that the Bill will be responsible for serious delays in research progress.

AusBiotech predicts a frenzy of legal activity will be necessary to interpret the language of the Bill and that parties will be tied up in the courts for what could amount to years of legal debate and cost.

For example, AusBiotech's reading of the Bill suggests that vaccines are at risk of exclusion from patentable subject matter. Whether our interpretation of the Bill language correct or not, this one example demonstrates the uncertainty around the Bill coverage and predicts the alarming prospect that the courts will be required to determine what is and what is not patentable subject matter on a case-by-case basis.

Such uncertainty will surely be a disincentive to investors as research timelines will blow-out and research costs will rise. It's also possible that such uncertainty coupled with the lack of investor confidence arising from the absence of patents for biological materials in Australia could spill-over into other parts of our economy and trigger real or perceived views of the country's sovereign risk.

The Bill will not benefit clinicians or researchers

AusBiotech rejects the Bill's premise that to "advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease" it is necessary to ban the patenting of 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.

Indeed, there is no evidence to support the notion that patents stifle research.

In the specific case of the Myriad gene patents, AusBiotech notes that the Australian Federal Court challenge of the validity of Australian patent number 686,004 came more than 10 years after the patent was granted in Australia. Notably, the patent will expire in 2015 making this technology largely redundant as a target. In the intervening time, there have been over 5,500 BRCA1 primary sequence publications. With no fewer than 49 Australian research organisations having contributed to this total, it is disingenuous for claims to be made that the existence of the Myriad patents has stifled research – at least in this field - to date.

Further, in a 2005 study[1] of 381 scientists, none had their work stopped by the existence of third-party patents and only about 1% had suffered a delay or were required to modify their work. Similarly, a new survey[2] of 3,350 individual Australian academic researchers reported few instances where access to patented research tools and/or materials was denied, although many did express a high degree of uncertainty about the research use exemption, which had, up until 2004, been thought to exist under common law.

In essence Australian researchers have enjoyed free and unfettered access to biological materials for many years. However, AusBiotech supports the amendment of the Patents Act to explicitly enshrine a research use exemption to patent infringement, applicable to all technologies. In this way, research, IP protection, innovation and commercialisation activities in Australia will continue to enjoy a beneficial coexistence. It is critical that Australian research institutes and universities be allowed to retain the source and the benefit of significant revenue derived from royalties payable on their licensed, patented technologies. The current Bill will place this income in jeopardy for researchers in public institutes or in industry alike.

The concerns expressed in relation to patents stifling research and access to medical technology are not unique to patents for genes or biological materials, indeed, these concerns can be applied equally to all technologies. Thus, it is significant that technology-neutral language around research use exemption will form part of IP Australia's draft reforms that are intended to improve IP rights legislation in this country to better support innovation and investment in all research and technology endeavours.

The Bill will not benefit patients

The claimed purpose of the Bill, to deliver free and unfettered access to biological materials, is not sufficient on its own to deliver new medicines and tests to Australians. Arguably the opposite is a more likely outcome with fewer innovative products and technologies reaching the community since the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia.

[1] http://www.sciencemag.org/cgi/content/summary/309/5743/2002

[2] http://www.ipria.org/publications/occasional%20papers/02-09%20Thomson%20&%20Webster.pdf

As the Government and our hospitals are not in the business of spending the millions, or billions, of dollars necessary to translate technologies from 'bench to bedside', Australia must rely on companies and financiers to take the risks and invest in the commercialisation of novel medicines and diagnostic technologies. This Bill is a tragedy in the making for a 'smart country' like Australia; Australian innovations will be lost as they follow the funding to the US, Europe and Asia. Global pharmaceutical companies may not include Australia in their market launch plans and ultimately Australians will have delayed access to new medicines and tests.

Patents are a primary incentive for investment in R&D and secure investors a fixed period of time in which to recoup their investment. The average cost of discovering and developing a new medicine is more than AUD$1 billion. The average development time for new medicines is 10-15 years. Without investment, Australian biotechnology companies are unlikely to survive let alone continue their R&D.

Without patent protection, global biopharmaceutical companies will have reduced incentive to develop their products for Australia. Further, companies may choose not to undertake clinical trials in Australia for these products if there is no prospect of marketing them. As a result, Australian patients could lose the opportunity for early access to innovative medicines and diagnostics through clinical trials.

The absence of patents for biological materials will extinguish the promise of future returns and thus discourage private foreign and domestic financiers to take on the risk and invest in product development. Without this investment, Australian research will stall at the early discovery phase.

Australia has been a global pioneer in a number of fields of technological endeavour and our scientists and industry can be justifiably proud of their home-grown innovations to improve the quality of life for people in Australia and all around the world via:

- the cochlear hearing implant (Cochlear);
- the cervical cancer vaccine (University of Qld, CSL, Merck); and
- a variety of diagnostics for breast and ovarian cancer, epilepsy, and TB (to name a few).

Other technologies with similar promise and global reach may suffer if this Bill is allowed to become law.

AusBiotech believes that the Bill has also completely failed to address the specific concern of the Australian public that stimulated the debate in the first place, that is, access to the BRCA diagnostic test.

Unquestionably, improved patient access to novel tests and therapies is essential. However, the community will be disappointed to find that a ban on patenting biological materials will have no impact on their ability to access specific tests and therapies.

Mechanisms to protect the public interest

Patents provide an exclusive period of time in which a patent owner may exploit their invention. Such limited monopolies are not responsible for the concerns being raised by the community; rather the potential problems arise from the behaviour of patent owners (be they universities, companies or individuals) when they act unethically or unreasonably in granting a license to a medicine, test or technology that is needed by the Australian community. In the event of such undesirable behaviour it should be dealt with by using the safeguards existent in the patents system.

The interests and needs of the Australian public can be protected via the safeguard mechanisms that already exist in the law. AusBiotech believes that a review of the Crown Use and compulsory licensing provisions that allow the government of the day or third parties to exploit a patent in certain circumstances is required followed by an effective legislative response to ensure these safeguards are adequate, efficient and accessible to all Australians. Never invoked in relation to the provision of healthcare in Australia, it may be that the spectre of these provisions within the patent system offers a degree of protection to the Australian community from undesirable behaviour in relation to the exercise of patent rights.

Further, AusBiotech suggests the establishment of a tribunal-like model and / or the appointment of a 'Patents Ombudsman' to whom the public, clinicians, researchers and industry could turn in the first instance with a grievance. AusBiotech believes the availability of such accessible and low-cost mechanisms would inspire a level of comfort and confidence to all Australians that their interests in these complex matters would be appropriately managed.

Such mechanisms to protect and improve public access to beneficial patented technology are reflected in the findings of several inquiries conducted over the years into the impact on human health issues of patent laws and practices. For example, the Australian Law Reform Commission Report 99 (ALRC99), 2004, recommended that "the Patents Act not be amended to exclude genetic materials or technologies" and concluded that patentability *per se* was not the mechanism by which concerns in relation to public access to patented gene-related inventions should be alleviated. The ACIP 2010 report on Patentable Subject Matter echoes this view in its comment that "Improving access to beneficial patented technology is better dealt with through mechanisms other than the test for patentable subject matter." Specifically, the ACIP 2010 report offered that where patient access to diagnostic tests or other medical treatments was being unreasonably restricted because of patents involving beneficial technologies encompassing biological materials, the remedy to the access problem could be found in a pricing mechanism and not in a mechanism that removed patent protection for the inventions.

Notably, no such mechanisms to protect public interests feature in the Bill.

One thing is certain, though, it is impossible to justify the calls being made by some stakeholders for more consultation. Already the consultation and review process has stretched over 10 years and has involved at least six inquiries, the most recent of which will not conclude until June 2011. AusBiotech is convinced that the public's interest in this matter will be best served by the Government considering the recommendations already before it, notably those from the ALRC99 report, the Senate Inquiry into Gene Patents (2010) and from the ACIP 2010 review, and also the proposed legislative changes in the pending Patents Amendment (Raising the Bar) Bill 2011.

Risking our International Standing

AusBiotech is informed that should Australia pass this Bill it will be in contravention of its obligations under TRIPS by discriminating against a field of technology (biological materials) for patent protection and also under its Free Trade Agreement with the United States.

Further, the Bill is inconsistent with recent events in the United States.

In March 2010, the Southern District of New York Court drew a distinction between DNA molecules and other biological material and ruled that the isolated DNA and cDNA sequences claimed in the Myriad patents-in-suit were unpatentable products of nature. Responding to this ruling, the US Department of Justice (DoJ) clearly distinguished between the patentability of isolated human genomic DNA and the patentability of a range of DNA materials when they are combined with human ingenuity such as in cDNAs, gene mutants and vectors. The DoJ has called for the US Federal Court of Appeals to uphold this critical distinction by reversing the District Court's invalidation of the claims limited to DNA molecules such as cDNAs and similar man-made nucleic acid products.

Regrettably, the DoJ's stand on this issue has been overstated and even misrepresented by some stakeholders participating in the debate in Australia.

Conclusion

AusBiotech has consulted widely and can report that patient advocacy groups, eminent researchers, research institutes, patent attorneys and the medical and agricultural industries all share serious concerns about the Bill and the negative unintended consequences it is likely to deliver.

Undeniably the hope of every Australian would be for a world-class health system that provides timely, safe and cost-effective access to essential treatments and life-enhancing medicines and technologies. Yet these hopes will be dashed if the Bill becomes law. The Bill will discourage innovation and investment in scientific and medical R&D in this country and thereby diminish or delay access to the longed-for cures and treatments for illnesses and diseases.

AusBiotech believes that the concerns and needs of the wider Australian community, including patients, clinicians, researchers and the biotechnology industry, will be better served by the Parliament focussing its energy on a review of the Australian Patents Act to ensure that, in relation to all technologies (including those involving biological materials and also those future technologies yet to be developed):

- patentability thresholds are properly set and rigorously applied;
- a research use exemption is enshrined in the law; and
- safeguards are readily-accessible and adequate in their reach to ensure all Australians have access to beneficial technologies; this will protect the Australian community against a patent owner who, in the course of exercising their patent rights, may act unethically or unreasonably in granting a license to a medicine, test or technology.

AusBiotech strongly suggests that an additional low-cost and accessible safeguard be established in the form of a tribunal-like model and/or the appointment of a 'Patents Ombudsman' to whom the public, clinicians, researchers and industry could turn in the first instance and with confidence that their interests in these complex matters would be appropriately managed.

AusBiotech urges the Committee to recommend that this Bill be rejected lest Australians be denied the improved access to health care that originally stimulated the debate.

Frequently Made Claims and AusBiotech's Response

The Bill is narrow	**Untrue** The Bill seeks to exclude <u>all biologicals</u> from patentability • genes, nucleic acids, proteins, vaccines, antibodies, mAbs, microbes (bacteria & viruses), antibiotics, enzymes, hormones, immunoglobulins and other blood products, stem cells, anti-toxins, anti-venoms, skin and other tissues, allergenics, probiotics, recombinant therapeutics …. • whether isolated or purified or not • whether identical or substantially identical • whether aquatic or terrestrial, vertebrate or invertebrate Diverse sectors of Australia's community will be negatively impacted • health care (vaccines, diagnostics and biopharmaceuticals, eg: for diseases such as arthritis, cancer & multiple sclerosis) • agriculture • animal production
The Bill seeks to clarify and apply existing law	**Untrue** The Bill seeks a wholesale change of the existing patent law by discriminating against biological materials. The Bill's ambiguous and vague language will require that the Courts determine what can and what cannot be patented. This will seriously delay the progress of medical research and drive up research costs.
The Bill will not prevent investment in biotech	**Untrue** The absence of patents for biological materials will extinguish the promise of future returns and thus discourage private foreign and domestic financiers to take on the risk and invest in product development.
The Bill will promote research and increase competition among researchers and lead to more tests and medicines	**Untrue** Since investment will no longer be available because of the absence of patents, it will be impossible to translate novel biological discoveries through the critical R&D stage gates such as proof-of-concept studies and clinical and regulatory trials. Consequently, Australians will have access to fewer new medicines and tests, not more.
Blocking access to a gene (via a patent) prevents open access for research to the human genome	**Untrue** Clinicians and researchers already have free and unfettered access to patented technologies – for research purposes. Confidence that clinicians and researchers do not face the threat of patent infringement can be enshrined in law by the inclusion of a research-use exemption.
The Bill will reduce research costs in relation to access to the "raw fundamental data of the human genome"	**Untrue** Clinicians and researchers can already access published human genome sequence data. It is mandatory that the contents of granted patents are published (unlike trade secrets, the details of which remain secret).

The Bill will improve patient access to diagnostic tests	**Untrue** The patent for the test itself will still be allowable under the Bill. Patient access to tests will not be improved one iota by the Bill.
The Bill does not affect Australia's international Trade obligations	**Untrue** Australia will be in contravention of its obligations under TRIPS by discriminating against a field of technology (biological materials) for patent protection.
Isolated genes are "a lawyers trick"	**Untrue** Isolated genes are man-made, free-standing molecules that, quite simply, do not exist as such in nature where they are an integral part of a larger entity such as a genome or chromosome.
The US Government supports a ban on patenting <u>all</u> biological materials	**Untrue** In fact, the US Department of Justice (DoJ) has called for the Federal Court of Appeals to <u>reverse</u> the District Court's invalidation of the claims in the Myriad patents that were directed to genomic DNA molecules such as cDNAs and similar human-engineered DNA products. The DoJ affirmed only that isolated but otherwise unmodified human genomic DNA is not patent-eligible subject matter.

Existing patent law protects the needs of the community	**True** Existing safeguards such as Crown Use and compulsory licensing can be relied upon where a patent owner is being unreasonable in relation to the granting of a license (ie: unacceptable monopolistic behaviour).
Human genes are products of nature - they are discoveries	**True** The mere identification of a gene provides no basis for securing a patent. However, when a gene sequence is isolated by human ingenuity to a free-standing, artificial environment in which its function and usefulness to mankind as part of a technology are described, it then deservedly becomes eligible to be patented.
Banning patents on biological materials will be detrimental to Australia's biotech and medicines industries	**True** Patents are a primary incentive for investment in R&D and secure investors a fixed period of time in which to recoup their investment. The average cost of discovering and developing a new medicine is more than AUD$1 billion. The average development time for new medicines is 12-15 years. Without investment, Australian companies are unlikely to survive let alone continue their R&D.
If the Bill had been in place 10 years ago, Australians would now not have access to many PBS listed therapies and vaccines.	**True** These vaccines and medicines would never have been developed for Australia because no company or financier would have been prepared to invest millions of dollars to bring them to market in this country without the security of financial return provided by composition of matter patents.
The Bill should be rejected	**True** The Bill must be rejected lest Australians be denied the improved access to the longed-for cures and treatments for illness and disease that stimulated the debate in the first place.

AusBiotech, Australia's voice on biotechnology represents more than 3,000 members encompassing medicines, medical diagnostics and devices, agriculture, alternative fuels and climate change.
The following has been developed as part of our contribution to the discussion around the patenting of genes.

What is being said by some stakeholders:	AusBiotech's response:
Australians must have access to life-changing medical tests, therapies and devices.	AusBiotech shares the view that all Australians should have access to world-class medical science. Indeed, Australian scientists and industry can be justifiably proud of their achievements in medical research to improve the quality of life for people in Australia and all around the world via: • the Cochlear hearing implant (Cochlear); • the cervical cancer vaccine (University of Qld, CSL, Merck); • a variety of diagnostics for breast and ovarian cancer, epilepsy, and TB (to name a few).
Human genes are discoveries not inventions.	AusBiotech understands that the DNA sequences of humans exist without any intervention of man and thus are not considered inventions.
Human genes should not be patented.	The mere identification of a new human gene is not an invention and is insufficient to secure a patent. Previous interpretation of patent law by Patent Examiners saw the granting of many broad patents worldwide that included claims for genes with little defined utility and also classes of similar nucleic acid molecules. It is very likely that this practice has contributed to the fears and concerns being expressed in the current debate. Poor examination did lead to granted patents that may not be valid. However, this practice no longer occurs as examination practices have been tightened. The success of the Human Genome Project has also contributed to the demise of past practices as a result of the freely-available publication of the vast majority of human gene sequences. Patent offices in Australia and elsewhere have tightened the interpretation of the thresholds for patentability (see below) to ensure that the mere identification of a new gene, in the absence of knowledge of its function and utility (ie. how practical use can be made of that knowledge) is not sufficient to secure a patent. AusBiotech supports the ongoing review of the legislation in this area to ensure that Australian industry and its researchers have a set of clear rules to guide them as they strive to innovate. In Australia today, it is possible to have a patent application that includes genes considered by the patents office providing that ALL of the following thresholds of patentability are met: • the gene or gene fragment is artificially-generated or isolated from its naturally-occurring environment; • the gene function is known and described in detail; and • the requirements of novelty, inventive step and usefulness are demonstrated and clearly documented (ie. isolated genes on their own, with no known utility, are not sufficient for a patent to be granted). In all cases, it is important to note that the inclusion of human gene sequences in a patent has never and would never give the patent owner any rights or ownership in relation to the gene(s) that exist in the human body.

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

What is being said by some stakeholders:	AusBiotech's response:
The existence of gene patents restrict patient access to tests and new medicines	Patents provide an exclusive period of time in which a patent owner may exploit their invention (up to 20 years). They do not stop someone else from developing a competing technology. Patents must disclose all details of the invention so that it can be repeated by anyone. As new technologies take many years to translate from the laboratory to a product of economic value, there is often only a few years of life left on a patent once the public has access to an invention (eg. work toward the Gardasil vaccine commenced in the early 1990s, the product was launched in 2008 and the original patent expires around 2012). Once a patent expires, the invention can be used by anyone. The temporary monopoly provided by patents actually reduces the risk of losing access to knowledge as might occur if scientists pursued their monopoly by maintaining the invention and research results as a trade secret rather than filing a patent application. Trade Secrets could restrict information flow in relation to a technology indefinitely and thereby impact the access of the general public to medical innovation. There are no safeguards built into the law to regulate how Trade Secret rights are exercised. A clear benefit of the patents system is the built-in safeguard provisions, such as Crown Use and Compulsory Licensing, which allow the government of the day or third parties to exploit a patent in certain circumstances. Never invoked in relation to the provision of healthcare in Australia, it may be that the spectre of these provisions within the existing patent system is sufficient to protect the Australian community from the hypothetically unethical behaviours of patent owners. To ensure that all Australians, including the public and the biotechnology industry, truly do believe that their interests are being protected by these safeguard provisions, AusBiotech believes that the processes and conditions around these provisions should be reviewed to confirm they are straightforward, intelligible, not cost-prohibitive and, thereby, readily accessible. Further, AusBiotech suggests the establishment of a tribunal-like model as the most approachable and effective method to ensure all Australians can access the existing safeguards. It is important to understand that in the case of the Myriad patents, the irony is that the called-for changes to Australia's patents law to ban the patenting of genes will not, as is claimed, improve public access to the BRCA diagnostic test as the very test itself remains the subject of valid patent claims. Of fundamental concern to AusBiotech is that any changes to gene-related patent law could follow the broad lines being called for by some commentators and extend far beyond human genes to include all biological materials. Should such sweeping change occur, the issue may become not one of public access to diagnostics, but rather that such potentially life-altering products are simply never developed.

What is being said by some stakeholders:	AusBiotech's response:
The existence of gene patents stifles research	There is little or no significant evidence to support this belief. Recent studies[1] concluded that of 381 scientists surveyed, none had had their work stopped by the existence of third-party patents and only about 1% had suffered a delay or were required to modify their work. Significantly, respondents to the question about costs required to access third party-patented technologies said the fee was in the range of US$1-100. Contrary to stifling research, having a patent granted means that all details of the invention must be published and thereby are available to anyone. Until 2004 it was believed that a common law research use exemption existed. ("Common law" refers to Judge made laws and is unrelated to the provisions of the Patents Act). Indeed, research activities and IP protection in Australia enjoy a continuing and beneficial coexistence. Nevertheless, to avoid the possibility of misinterpretation, IP Australia is currently advancing the amendment of the Patents Act to introduce a research use exemption. AusBiotech is in favour[2] of there being a research exemption to patent infringement to enable researchers to proceed with their work so long as the activity is not commercial in nature and looks forward to seeing the recommended changes from IP Australia arising from their consultation process. Additionally, AusBiotech believes that any amendments should be made to best serve Australia's national and international interests, are 'inclusive' and explicitly remedy the current legal ambiguity and provide clarity to Australian researchers in relation to exemptions for experimental purposes. In the specific case of the Myriad gene patents, AusBiotech notes that the Australian Federal Court challenge of the validity of Australian patent number 686,004 came more than 10 years after the patent was granted in Australia. In the intervening time, there have been 5,674 BRCA1 primary sequence publications, of which 1933 (34.1%) were from the US while 184 (3.2%) originated from Australia (Ref: PubMed and ISI Web of Knowledge). With no fewer than 49 Australian research organisations having published their research results over the past 12 years it appears disingenuous for claims to be made that existence of the Myriad patents has stifled research – at least in this field to date. On the flip side, Australian research institutes hold more than 1200 patents many which include gene sequence claims. In a recent survey[3] of 3350 individual Australian academic researchers few reported instances where access to patented research tools &/or materials was denied, however, there was a high degree of uncertainty among the respondents about the research use exemption of patents. As discussed above, IP Australia is already taking steps to remove any doubt in the mind of Australian researchers on the latter point.

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

What is being said by some stakeholders:	AusBiotech's response:
If patents over biological materials are banned the process of discovery and invention will be improved	Patents are frequently part of the package that innovators use to attract critical funding to progress early research through to the proof-of-concept stage. The data generated from this early phase of the journey can then be used to attract the substantial investment needed to complete the development of a new piece of biotechnology, whether it is a medicine, a device or a diagnostic tool. As recipients of significant public funding, Australian universities and research institutes embrace the intellectual property system, including patents, to: • inform and advance their research programs; • provide a platform for collaborations with industry; • secure investment and income stream from technology licensing deals; • define rights and ownership over materials and inventions; • support career progression, and • assist in the translation of research innovation. AusBiotech contends that the biotechnology industry in this country regards patents in precisely the same way as do Australian universities. At a cost of hundreds of millions of dollars, many companies will have multiple research programs advancing simultaneously along the development pipeline to guard against the high attrition rates and lengthy development timeline for a novel medical invention to reach the market. Patents are an important element in the value proposition that both public and private investors study before making a decision to invest. Logically, any reduction in investment will correlate with a decrease in the number of new drugs and diagnostic tests being developed. In the event that the current incentives for corporate and venture capital investment in the form of gene patents disappear, AusBiotech poses the question as to who will partner with public research institutes and biotechnology companies to provide the money and development capability to translate Australian inventions from 'bench to bedside.' Governments are not in the business of bringing therapeutics and diagnostics to market and so we rely on corporates and VCs to invest the money and take the risks to develop novel medicines and diagnostic technologies and bring them to market. Although unintentional, it is difficult to see how the impact of broad changes to the Patents Act will be anything other than a reduction in capital for research commercialisation with the direct consequence being a reduced number of products that reach patients. It is important to note that the ramifications of a ban on the patenting of biological material would extend far beyond the medical sciences with serious negative impacts likely on innovation efforts directed at improving the health and productivity of plants and animals.

What is being said by some stakeholders:	AusBiotech's response:
We need the banning of gene patents	Following through on the call to ban gene patents will not necessarily deliver solutions for the issues that some stakeholders are articulating. For example, as is the case with the BRCA diagnostic test, patient access to new medicines and diagnostics will not be improved by placing a ban on gene patents. Rather, if the proposed changes are too broad new medicines and diagnostics will simply not be developed and no-one will benefit. Instead, positive impacts on the health and well-being of all Australians can be envisaged if there is broad and inclusive consultation to examine the current legislation leading to, where necessary, clarification and strengthening of the relevant clauses of the Patents Act. AusBiotech's approach to solving the complexities of this issue would be effective and will not result in the unintended consequences that may result should there be extensive changes made to the Patents Act. Further, AusBiotech and the industry are open to working productively with IP Australia and the Parliament to deliver improved clarity in this area. AusBiotech's overriding concern is for the achievement of ongoing patient access to new medicines and diagnostics which is intrinsically linked with the optimisation of Australian innovation.

1. http://www.sciencemag.org/cgi/content/summary/309/5743/2002
2. http://www.ausbiotech.org/data/downloads/April%202009%20-%20Response%20to%20IP%20Australia%20Exemption%20to%20patent%20infringement.pdf
3. http://www.ipria.org/publications/occasional%20papers/02-09%20Thomson%20&%20Webster.pdf