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.

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

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 <u>providing that ALL</u> 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.

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.

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