

Fact sheet: gene patenting in Australia  
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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 fact sheet has been developed to provide a further perspective in response to a sustained public campaign calling for the banning of gene patents.

- Patents provide certainty to encourage public & private investors to fund innovation and research.
  - A patent is a legally enforceable, exclusive limited right granted to an owner of a device, substance, method or process, to exploit the invention for the life of the patent (typically up to 20 years).
- For a gene-related invention to be patentable in Australia the nucleic acid molecule must be isolated from its naturally-occurring environment and some use made of that molecule.
  - While patents may be granted for an isolated nucleic acid molecule that may mimic the function of a gene in a cell, those patents do not cover the natural genes in our bodies.
- The granting of a patent, whether it be for a clothes line or a gene-related technology, is not automatic and comes about only if the application meets the legal requirements for patentability.
  - Applications to the Patent Office are only granted following rigorous examination to establish **novelty, inventive step** and **usefulness**.
- The patent system does not stifle research.
  - The patent system encourages innovators to disclose their invention so that information may be used by the public to advance the technology or field.

- To avoid the possibility of misinterpretation, IP Australia is currently progressing the introduction to Australian law of an exemption from infringement for individuals whose use of an invention occurred in the context of non-commercial research.
- Current Australian law includes safeguards against monopolistic behaviours of patent holders.
  - It is reasonable to expect a balance between the exclusive rights of the innovators and investors and the rights of the wider scientific community and of the general public to access new information and technologies. Australian law has safety provisions such as crown use and compulsory licensing to allow the government or authorised third parties to exploit a patented invention in certain circumstances.
  - Crown use and compulsory licensing provisions have not been invoked in relation to the provision of healthcare because the interests of the Australian community have generally been well served by the existing patent system through access to patented inventions.
- Without incentives for investment in innovation and R&D, the speed and frequency of development of new medicines and tests will diminish.
  - Patents are often part of the package, which companies use to attract modest, yet critically sustaining, funding to help progress early research through to proof-of-concept. Subsequently this data can be used to attract the substantial investment needed to complete the development of a new medicine or diagnostic test.
- The health and well-being of the Australian public may suffer by a reduction in the development of new medicines and tests.
  - Today many companies will have a 'number of shots on goal' being advanced along the development pipeline simultaneously. Understandably this multiplies development costs but with less money in the system, there will be manifold-less candidates in development. Given the high attrition rates and development timeline of 12-16 years for a new medicine to reach the market, diminished investment in research and innovation will lead to fewer new medicines and tests reaching the market.
- The called-for changes to the patents law in Australia to ban the patenting of all biological materials and their use will not, as is claimed, guarantee public access to new medicines and tests. Arguably this would likely result in the withdrawal of investment by the corporate sector and thereby a dramatic reduction in medical and biological research.
- Consequently, the issue may become not one of public access to novel medicines and diagnostics, but rather that such potentially life-altering products are simply never developed.